

Review and Evaluation of Proposed Legislation Entitled: An Act Relative to Establishing the Massachusetts Childhood Vaccine Program and the Massachusetts Immunization Registry Senate Bill 2195 (House Bill 3453)

Provided for The Joint Committee on Health Care Financing

August 2010



Table of Contents

Executive Summary	1
Introduction	8
Background	12
Methodological Approach	21
Summary of Findings	24
Endnotes	30

Appendix:

Actuarial Review of Massachusetts Senate Bill 2195 (House Bill 3453), An Act Establishing the Massachusetts Childhood Vaccine Program and the Massachusetts Immunization Registry

Executive Summary

This report was prepared by the Division of Health Care Finance and Policy (DHCFP) pursuant to the provisions of M.G.L. c. 3 § 38C which requires DHCFP to evaluate the impact of mandated benefit bills referred by legislative committee for review, and to report to the referring committee. The Joint Financial Services Committee referred Senate Bill 2195 (S.2195) "An Act Relative to Establishing the Massachusetts Childhood Vaccine Program and the Massachusetts Immunization Registry" to DHCFP for review.

Vaccine and Immunization

Note that the terms "vaccine" and "immunization" are often used interchangeably in this report. However, these terms are defined, here, by the Centers for Disease Control and Prevention (CDC) to distinguish vaccine from immunization as follows. A vaccine is: "a product of weakened or killed microorganism (bacterium or virus) given for the prevention or treatment of infectious diseases." Immunization is defined as "a process or procedure that increases an organism's reaction to antigens, thereby, improving its ability to resist or overcome infection."

Health Insurers and Health Plans

Throughout this report, the term "health insurer" is used to include all fully-insured and self-insured health plans, the Group Insurance Commission and MassHealth. On the other hand, the term "health plan" is used to refer only to fully-insured plans. We make this distinction because part of this bill (the assessment) applies to all insurers including self-insured plans and potentially MassHealth, while the mandate for coverage does not apply to self-insured plans because they are exempt from state mandates under the federal Employment Retirement Income Security Act (ERISA) of 1974.

Application of the Mandate and Assessment to MassHealth

It is important to note that S. 2195, as written, applies both the vaccine mandate and the assessment to MassHealth. On the one hand, as noted in Appendix 1, DHCFP concludes that that the evidence was insufficient to calculate the financial impact of a vaccine mandate on MassHealth. In addition, provisions of M.G.L. c.3 S.38C requires DHCFP to evaluate the impact of mandated benefits on the premiums paid in the privately insured market and does not apply to MassHealth. Furthermore, MassHealth members currently receive vaccination coverage through federal and state resources. DHCFP concludes that there are a number of related financial and policy considerations that merit a closer examination, including the potential financial impact on MassHealth of the proposed bill's requirements to reimburse "any willing provider" at 100 percent of reasonable and customary charges for vaccines and costs for administration and its consequent effect on federal financial participation (FFP). DHCFP also concludes that the assessment could have an impact on MassHealth. DHCFP does not, however, intend to suggest that application of the assessment would work with all applicable federal laws and regulations. For example, all Medicaid-eligible children are eligible for federally-purchased vaccines through the federal Vaccines for Children Program (VFC). The federal VFC program provides universal access to all vaccines recommended by the Advisory

Committee on Immunization Practices (ACIP) to all individuals under the age of 19.² Furthermore, it is important to note that DHCPF currently has the authority to assess surcharge payors through the state fiscal year 2010 budget. MassHealth is currently excluded from any assessment, however.

National Context

According to the American Task Force on Immunizations, "vaccines are the most cost-effective and life-saving interventions of modern medicine." "Over the lifetime of each birth cohort in the United States, routine vaccination of children and adolescents prevent 14 million VPD cases and 33,000 VPD deaths."

In recent years, however, protecting the public health has become a financial challenge, due to the increasing number of recommended vaccines and the relatively high cost of new vaccines. Over the past couple of decades, immunization costs have increased significantly. From 1995 to 2008, the cost for providing all recommended vaccines to children through age 18 increased between \$150 and \$223 per child to \$1,407 per girl and \$1,105 per boy.⁵

These financial challenges have led some states to consider new ways to finance immunization coverage through private financing from health insurers. New Hampshire and Idaho, for example, have established vaccine associations for the purpose of streamlining the purchase and distribution of vaccines with monies collected from health insurers. The state of Washington recently enacted a law to assess health insurers modeled after New Hampshire's law. Vermont is embarking on a new pilot program.

As proposed, S. 2195 seeks to make immunization coverage for Massachusetts residents more comprehensive through private financing and to contain spending on vaccines for insurers through the use of the federal procurement system for vaccines.

Overview of Current Law and Proposed Mandate

Senate Bill 2195 has significant policy and financial implications for the state, health insurers, the Group Insurance Commission (GIC), MassHealth, health-care providers, and residents. The intent of the proposed legislation is to ensure that children receive universal access to immunization coverage, in accordance with the most recent schedules recommended by the Advisory Committee on Immunization Practices (ACIP) of the U.S. Department of Health and Human Services, and that adults receive improved access.

Senate 2195 proposes the following provisions. These provisions are described in more detail below:

- A childhood immunization fee, otherwise known as an assessment
- A vaccine mandate requiring health plans to reimburse for immunizations in accordance with the Advisory Committee on Immunization Practices (ACIP)
- An immunization registry.

Assessment

S. 2195 includes a proposal to establish the Vaccine Purchase Trust Fund into which all health insurers, including fully-insured plans, self-insured plans, the GIC, and potentially MassHealth, would pay an assessment. This assessment is referred to as a "childhood immunization fee." The trust fund would be used for the purpose of establishing a universal purchase, storage and distribution of routine childhood vaccinations. The proposed bill also establishes a "vaccine purchase advisory council." Total assessments would be calculated on the basis of the total requirement to support the purchase of routine childhood vaccines net of federal funding. MDPH and DHCFP would work together to determine which vaccines are purchased and the non-federal program costs. The purchase and distribution system for vaccines would be subject to regulations developed by MDPH.

Current law does not require health insurers to pay an assessment. However, the state fiscal year budget for 2010 provides the state the authority to assess health insurers for pediatric vaccines. This assessment was implemented by DHCFP during fiscal year 2010 and applied to all surcharge payors, but will expire at the end of fiscal year 2010. MassHealth is currently excluded from this assessment for state fiscal year 2010. As of this writing, it is not yet determined whether DHCFP will retain its authority to assess health insurers for a future year.

Vaccine Mandate

S. 2195 introduces a "vaccine mandate," requiring all health plans, the GIC and MassHealth to provide immunization coverage in accordance with the most recent schedules recommended by the Advisory Committee on Immunization Practices (ACIP). Self-insured plans are excluded from this mandate, since self-funded plans are exempt from state mandates under the federal Employment Retirement Income Security Act (ERISA) of 1974.

In addition to the vaccine mandate, health plans would be required to provide first-dollar coverage for vaccines. Under a policy of first-dollar coverage, members would be exempt from having to pay any copayment, coinsurance, deductible, or dollar-limit provisions in the health-insurance policy or contract. Presumably, the intent of this provision is to encourage primary prevention of disease and to reduce any financial barriers affecting access.

S. 2195 would also require that health plans reimburse providers at "100% of the reasonable and customary charges" for immunizations and "any reasonable and customary costs" associated with the administration of the vaccines.

Current law mandates that fully-insured health plans provide immunization coverage from birth to 6 years old. Current law does not mandate that health plans provide immunization coverage in accordance with the recommendations of the ACIP. Typically, however, health plans adhere to the policy of providing coverage for immunizations to children based on the ACIP schedule, with health plans providing coverage for pediatric vaccines that are not universally supplied by the state.⁶ Health plans also reimburse for administration.

In addition, a review of the claims data indicates that self-insured plans also provide immunization coverage. Finally, MassHealth provides vaccine services through a combination of state and federal sources.

The Massachusetts Immunization Registry

S. 2195 proposes to establish an immunization registry for Massachusetts. The purpose of this registry is to provide the state with a system for tracking vaccine coverage in the Commonwealth for the prevention and control of disease. Licensed health-care providers who administer vaccines would report all data related to immunizations to the registry. The registry would be supported by the Vaccine Purchase Trust Fund, and implemented in accordance with regulations established by the state. According to the Massachusetts Department of Public Health (MDPH), the advantages of such a registry would be several, including: providing immunization-decision support for providers, reducing administrative burden for providers and schools, reducing vaccine waste and over immunization, and improving accountability. Most importantly, a legal framework for a registry would allow MDPH to establish an "opt-out" system to ensure successful implementation of a fully-populated system.⁷

Current law does not include an adequate legal framework to establish an immunization registry. Current law requires MDPH to adhere to an "opt-in" consent process only. To date, MDPH has received one-time funding to begin development of the registry.

Methodology for Financial Impact Analysis

The Division prepared this review and evaluation of S. 2195 by conducting interviews with legislative staff, insurers, and public-health officials, reviewing the relevant literature, interviewing industry experts relative to immunization coverage, and conducting an actuarial analysis of the fiscal impact of S. 2195 (see Appendix).

DHCFP's analysis focused on estimating: (1) the impact of the vaccine mandate; and (2) the impact of the assessment.

1. Impact of the Vaccine Mandate: The impact of the vaccine mandate was estimated based upon a determination of the additional amounts to be paid above current costs for vaccines and administration in compliance with the mandate's proposed requirements to provide first-dollar coverage and to pay any willing health-care provider 100 percent of reasonable charges for vaccines and costs associated with administration. Appendix 1 provides the financial results of the vaccine mandate for health insurers, including all fully-insured and the Group Insurance Commission. The impact of the mandate on self-insured is also presented separately in the appendix for information; however, as previously noted, DHCFP interprets the proposed legislation to exclude self-funded plans from the mandate, since they are exempt from mandates under federal ERISA laws. Financial results for the vaccine mandate are not provided for MassHealth, since there is insufficient evidence upon which to develop such a calculation.

- Three different impact scenarios were developed low, middle, and high to present a range of the possible impact of the proposed mandate on premiums and total health plan expenditures.
- 2. Impact of the Assessment: The impact of the assessment was estimated by applying the assessment to all health insurers under an illustrative scenario that allocates a fixed assessment amount across all health insurers, including MassHealth. This methodological approach should be viewed as illustrative only, since the proposed legislation does not set forth a methodology for allocating the assessment across insurers.

DHCFP applied the assessment to MassHealth, since the language of the bill requires that all health insurers, including all fully-insured and self-insured health plans, the Group Insurance Commission and MassHealth, comply with the assessment. In addition, subsequent communication from the Committee on Health Care Financing outlines the intent of the bill to include MassHealth in that assessment. DHCFP advises, however, that the reader also consider a more thorough examination of all state and federal laws, as well as an understanding of the role of federally-purchased vaccines for children, in determining if the assessment, in part or in total, can or should apply to MassHealth. The current assessment, for example, does not apply to MassHealth. Should the proposed bill be enacted with provision to exclude MassHealth from an assessment, a recalculation of the financial impact on each insurer facing an assessment would be required. Such a recalculation would lead to a higher projected impact on fully-insured and self-insured health plans in response to a reallocation of the fixed assessment amount.

Finally, the total assessment amount was developed based upon a determination of the total non-federal program costs that health insurers would be expected to finance should the proposed bill be enacted. DHCFP's consultants defined total non-federal program costs to represent the current assessment that fully-insured and self-insured health plans pay to DCHFP, based on the authority provided to DHCFP through the state fiscal year 2010 budget. The total assessment amount reflects the purchase of vaccines for health insurers at the CDC-negotiated purchase price. The total assessment amount excludes HPV costs that are currently covered by health insurers. Note that including the costs of HPV to insurers would lead to an increase in the amount of the assessment to health insurers, but would be certain to offer health insurers a cost reduction over current spending for HPV, as a result of the benefit that including HPV in the federal procurement process for vaccines.

Appendix 1 provides the financial results of the assessment for all health insurers, including all fully-insured and self-insured health plans, the Group Insurance Commission and MassHealth.

Results of Financial Analysis

Summary Results: Vaccine Mandate and Assessment

The results that are most relevant to the legislative review of the proposed legislation are presented in this summary section in Exhibit 1.

Mandate: In 2011, the projected increase in spending that would result from the vaccine mandate – affecting fully-insured health plans including the GIC – represents an increase in premiums of \$18.4 million or \$0.65 per member, per month. See Exhibit 1 for these results. Exhibit 3 shows that this translates to \$97.6 million over a 5-year period.

Assessment: The illustrative impact of the assessment which applies to all fully-insured and self-insured plans is an additional \$38.3 million per year and reflects an additional \$0.72 per member per month for commercial plans (fully and self-insured) (see Exhibit 1). The illustrative impact of the assessment for MassHealth is determined to be an additional \$15.8 million per year beginning in 2011.

Combined for fully insured: *The combined effect of the mandate and the assessment for fully-insured commercial plans is an additional \$1.38 or 0.31% of premiums.*

It is important to note that the financial results in Exhibit 1 include the impact of the vaccine mandate on fully-insured health plans and the impact of the assessment on all health insurers, including fully-insured and self-insured health plans and MassHealth. Note that the separately reported results for the vaccine mandate for the Group Insurance Commission reflect the fully-insured GIC membership. Also note that DHCFP presents the financial results for the vaccine mandate for self-insured plans in the appendix, although the reader can assume that self-funded plans are exempt from state mandates under the federal Employment Retirement Income Security Act (ERISA) of 1974.

The 2011 financial results reflect the middle-impact scenario for the vaccine mandate, and the only scenario provided for the assessment. Note that Appendix 1 provides the comprehensive set of results for five fiscal years 2011-2015 and for all three scenarios for the vaccine mandate (low, middle, and high).

The results by health insurer, including the illustrative results for the assessment, are summarized, here:

- Fully-insured plans. In 2011, the projected increase in spending that would result from S. 2195 translates to an increase in premiums of \$39 million for fully-insured health plans. The impact on the per member per month (PMPM) premium would be \$1.38. These numbers reflect the impact of the middle-case scenario for both the vaccine mandate and the assessment on fully-insured plans, and would increase the premium for fully-insured health plans by .31%. Over half of that increase is due to the assessment.
- Self-insured plans. In 2011, the projected increase in spending that would result from the assessment defined in S. 2195 translates to an increase in premiums of \$17.7 million, or \$0.70 per member per month for self-insured plans. Over a 5-year period this totals \$94 million. Self-insured plans are not assumed to be subject to the mandate portion of the bill due to ERISA laws; however, estimates are provided in the actuarial report appendix.
- MassHealth. In 2011, the projected increase in spending that would result from the assessment defined in S. 2195 is \$14.9 million for MassHealth, should it be determined that the assessment applies to MassHealth. The 2011 fiscal impact of the assessment on MassHealth is shown in Exhibit 1. We have excluded a discussion of the impact of the mandate from consideration in this report, since there is no evidence to indicate an impact.

Exhibit 1: Estimated Cost Impact of S.2195 on Health Care Premiums

Plan Category	Fully-Insured including GIC ^b	Self-Insured including GIC ^b	Commercial ^b	MassHealth ^b	Total ^b
Enrollment	2,356,000	2,097,000	4,453,000		
Premium Impact (Millions)					
Vaccine Mandate ^a	\$18,437		\$18,437		\$18,437
Assessment	\$20,568	\$17,730	\$38,298	\$14,900	\$53,198
Total	\$39,005	\$17,730	\$56,735	\$14,900	\$71,635
PMPM Impact					
Vaccine Mandate	\$0.65				
Assessment	\$0.73	\$0.70	\$0.72		
Total	\$1.38	\$0.70			

^a Financial results for the vaccine mandate are provided for fully-insured plans only. The vaccine mandate is not expected to apply to self-insured health plans, because self-insured plans are exempt from state mandates under the federal Employment and Retirement Income Security ACT (ERISA) of 1974.

^b Numbers in "bolded text" are most relevant to legislative review and evaluation of S.2195.

Introduction

In the United States, states and localities have primary responsibility for protecting the public health. Many states supplement federal funding with state funding to ensure that coverage is universal.

In Massachusetts, the legislature has historically supplemented federal funding with state funding to ensure that all children and high-risk, uninsured adults at public sites have access to vaccines, relying upon a system of purchasing and distributing vaccines to healthcare providers at no cost. In recent years, however, the state's universal immunization system has experienced increasing costs as a result of the ever-increasing number of new vaccines and relatively expensive vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) of the U.S. Department of Health and Human Services. Subsequently, the Massachusetts Department of Public Health (MDPH) was forced to exclude the human papillomavirus vaccine (HPV) from the supply of vaccines purchased and distributed to healthcare providers. Public-health officials grew concerned about the ethical dilemmas facing health-care providers and the related impact on the equity of such a system, with concerns greatest for the "underinsured."

The state budget for fiscal year 2010 includes the requirement that all surcharge payors as defined in section 34 of chapter 118G of the General Laws pay an assessment fee, thereby shifting the cost of historically state-funded vaccines to private payers. This assessment fee applies to both fully-insured and self-funded plans. This assessment provision expires at the end of state fiscal year 2010, however, leaving Massachusetts with questions about financing immunization coverage in the future. The assessment does not currently apply to MassHealth.

The remainder of this introductory section summarizes the scope of the current law and describes how private insurance coverage would change under the proposed bill.

Summary of Current Law

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Vaccine Mandate / Health Plans

Current law requires that fully-insured health plans provide immunization to children from birth to 6 years old. Current law does not apply to adults. If enacted, Senate 2195 introduces several new legal requirements for health plans, including that all health insurers provide first-dollar immunization coverage for children and adults, and that health-care providers are reimbursed at 100 percent of reasonable and customary charges for vaccines and costs for administration. (These provisions would not be enforceable for self-insured health plans, however.)

Health plans in Massachusetts typically cover immunizations for children based on the recommended immunization schedule for children and adults of the ACIP. Current law does not require that health plans comply with ACIP recommendations.

Assessment / Health Insurers

The state fiscal year 2010 budget for Massachusetts includes a provision to establish the Pediatric Immunization Program Assessment. This assessment will expire at the end of the state's fiscal year. See Box 1 for a summary of the Pediatric Immunization Program Assessment currently in effect for state fiscal year 2010.

Box 1: Pediatric Immunization Program Assessment

Massachusetts established the "Pediatric Immunization Program Assessment" through Section 47 of the state budget for fiscal year 2010. This section will expire at the end of state fiscal year 2010. Senate 2195 would make permanent the requirement that health insurers pay for the non-federal program costs of providing pediatric vaccines to children. Historically, the state has funded the non-federal program costs of providing pediatric vaccines to children on behalf of health insurers. Should S. 2195 be enacted, health insurers would be required to share in the cost of providing for the public health. Section 47 of the budget is provided below, in addition to a brief summary of the administrative bullet as provided by DHCFP:

Section 47: "Notwithstanding any general or special law to the contrary, each health insurance carrier, as defined in chapter 1760 of the General Laws, that conducts business in the commonwealth shall contribute to the total amount determined by the department of public health to be sufficient to cover the costs of purchasing and distributing childhood vaccines for children in item 4580-1000 of section 2 of this act. The division of health care finance and policy, in consultation with the department, shall specify by regulation the method of calculating a proportional contribution and procedures for payment of the contribution to the General Fund."

Administrative Bulletin 10-03 Effective January 22, 2010, entitled: "Chapter 1760 of the General Laws: 114.5 CMR 20.00: Pediatric Immunization Program Assessment." "This is to notify payers that the Division of Health Care Finance and Policy (Division) has determined that the FY 2010 Pediatric Immunization Program Assessment surcharge percentage is 1.56%. This Assessment is authorized by Line Item 4580-1000 of Chapter 27 of the Acts of 2009, as amended by Section 47 of Chapter 120 of the Acts of 2009, and Regulation 114.5 CMR 20.00. Based on available Health Safety Net surcharge payment data, the Division has determined that the assessment percentage of 1.56% will generate approximately \$46.6 million, as required by the statute. Each payer must calculate its assessment liability by applying the 1.56% to its payments made to hospitals and ambulatory surgical centers from January 1, 2010 through April 30, 2010, according to the schedule in 114.5 CMR 20.03(5)(b)."

Summary of Proposed Bill

The intent of Senate Bill 2195 is to create a framework for financing universal immunization coverage and for achieving maximum coverage among children and adults by addressing current barriers and establishing the foundation for shared public-private responsibility for the protection of the public health. It is important to note, again, that the mandate does not apply to self-insured health plans.

More specifically, S. 2195 requires health insurers to pay for all vaccines that are not provided by the federal government, including those costs that have historically been paid by the state. The key elements of this framework include:

- Health insurers would be required to pay an assessment for vaccines, in keeping with the concept of the pediatric assessments that began in fiscal year 2010.
- Health plans would be required to provide immunization coverage. As written, the proposed mandate would apply to the fully-insured market, including health maintenance organizations (HMOs) and Blue Cross Blue Shield plans, the Group Insurance Commission, and MassHealth.
- The Commonwealth would establish an immunization registry. See Box 2 to read more about an immunization registry.

Senate 2195 also includes several additional provisions to support a universal purchase and distribution system, including:

- Administrative Structure. The proposed bill includes the establishment of the Vaccine
 Purchase Trust Fund into which the assessments from health insurers would be deposited.
 The bill also proposes to establish the Vaccine Purchase Advisory Council for the purpose of
 recommending vaccines to be purchased.
- First-dollar coverage. The bill proposes to exempt members from any out-of-pocket costs for immunization coverage.
- Reasonable and customary reimbursement for providers. The bill proposes the following requirements for health plans relative to reimbursement. Health plans would be required to pay: (1) non-network providers for immunization coverage; (2) "100% of the reasonable and customary charges" for immunizations, excluding those costs covered by the state or federal governments; and, (3) "any reasonable and customary costs" associated with the administration of the vaccine.

Box 2: Immunization Registry

State immunization registries are part of a national and state-wide effort to assess rates of immunization among children. Massachusetts is one of only three states in the country without an immunization registry. Kentucky and New Hampshire are the other two.

At this time, the CDC collects immunization data from the National Immunization Survey and School and Childcare Vaccination Surveys. Schools and childcare facilities presently shoulder the administrative burden of providing this information. A state registry has the potential to greatly facilitate the flow of this information and ease the burden on community partners. Should Massachusetts establish an immunization registry, a single source of data would be accessible to all community-immunization partners.

What is an immunization registry? An immunization registry is a confidential and computerized-information system that contains data on vaccine coverage for children within a geographic area. The CDC and the American Immunization Registry Association have developed a set of core data items, required and optional, that a registry should contain.⁸

What can an immunization registry do? An immunization registry can be used to improve immunization practice and facilitate important health and assessment functions by improving coverage. A web-based registry should include the capability to: assist healthcare providers to ensure children are up-to-date with their immunizations; improve coverage by providing more accurate records, especially for low-income and under-insured populations, and for identifying the need for additional immunizations; and provide the infrastructure needed for tracking coverage during emergency situations.

How does a registry work? A web-based registry would allow health-care providers to enter immunization data for a patient directly into the registry via the web in exchange for a consolidated record of vaccinations from multiple healthcare providers. Such a system could serve to reduce vaccine wastage and prevent unnecessary duplication. Registries might also provide reminders to health-care providers when a vaccine is due or being recalled; or, maintain official immunization records that are required by law for children to enter school or a childcare facility.

How can a registry help in emergency and disaster situations? Immunization registries can provide the infrastructure needed to track essential information and to identify children at risk in the event of a disease outbreak, influenza pandemic, natural disaster, bioterrorist events or other infectious disease emergencies. In the aftermath of Hurricane Katrina, Louisiana used its web-based registry to provide immunization data for children relocated to other states. Health-care providers in other states were able to access 55,000 records that were then used for immunization purposes or entry into school.

Background

In this section, the Division provides: (1) background information on the universal immunization requirement for Massachusetts; (2) an overview of federal and state funding sources for vaccines; (3) information about the cost of immunization coverage, including the cost of vaccines, the pricing discounts available through the Vaccine for Children program, and reimbursement for immunization coverage; (4) a synopsis of existing health-insurance coverage by health plans in Massachusetts; and (5) a summary of federal and state activity, including an overview of immunization coverage in New England.

Massachusetts: Requirement to Provide Universal Immunization Coverage.

By law, the Massachusetts Department of Public Health is required to establish a universal immunization program. Massachusetts has historically fulfilled this requirement by purchasing and distributing vaccines on a universal basis. Massachusetts Department of Public Health (MDPH) has supplied all routinely-recommended pediatric vaccines to all public and private providers to vaccinate all children through a combination of federal and state funding. State funding has served to neatly supplement federal funding for pediatric vaccines to cover the non-federal program costs of covering all vaccinations for all children, regardless of health status, in accordance with the recommendations of the Advisory Committee on Immunization Practices (ACIP). A small amount of the state monies have also been allocated to purchase adult vaccines.

Today, Massachusetts is now considered a universal-select state, because it does not provide funding for HPV.

Federal and State Funding Sources for Vaccines

Historically, Massachusetts has funded its universal system of purchasing and distributing vaccines through three funding streams: (1) the federal Vaccines for Children (VFC) program; (2) the federal Section 317 grant program; and (3) state monies. Combined, these funding streams total more than \$100 million on an annual basis.

A review of the claims data shows that health insurers, including fully-insured and self-insured plans, spend approximately \$76.8 million on vaccines. That amount includes what health insurers spend on the human papillomavirus vaccine (HPV) but excludes spending by health insurers on administration. Administrative costs add another \$46.9 million.

Spending by MassHealth is not included in this section. However, all other federal and state funding streams are described below.

The VFC Program

The VFC program was established as part of the Omnibus Reconciliation Act of 1993 (OBRA '93) to improve the availability of vaccines nationwide. Section 1928 of the Social Security Act establishes the program for the distribution of publicly-purchased vaccines to eligible children at no charge to public and private health care providers. VFC-eligible children must be under 19 years of age

and meet at least one of the following criteria, including: Medicaid eligible; uninsured; American Indian or Alaska Native; and underinsured. Underinsured children are only eligible to receive VFC-vaccines in a federally-qualified health center or rural-health clinic. This federal source of funding supports all vaccinations for VFC-eligible children that are recommended by the Advisory Committee on Immunization Practices (ACIP) of the U.S. Department of Health and Human Services.

Section 317 Immunization Grant Program

The federal government also provides Massachusetts with funding through Section 317 of the Public Health Service Act. This program provides funding that can be used to purchase vaccines for children and adults, and to support state-immunization operations and infrastructure. These federal vaccine dollars are currently maintained by the CDC and are used to supplement VFC dollars.

State Appropriation

Through line-item appropriation in the state budget, Massachusetts has historically devoted monies to pay for the purchase and distribution of vaccines to public and private providers for children and adults who are not eligible for the VFC program. Monies spent on providing vaccines for adults have represented only a small percentage of the state appropriation.

The Marketplace for Vaccines

According to the Centers for Disease Control and Prevention, (CDC), there are 54-licensed vaccine products. Collectively, these vaccines offer protection against over 20 infectious diseases.¹² The Food and Drug Administration (FDA) is responsible for approving all vaccine products for market, after a long process of research and development to ensure safety and medical efficacy of their product. The time period for the development of some products can take years, as it did in the case of HPV.

The size of the vaccine market is small, with instances of only one manufacturer for certain vaccines. The cost structure of vaccine production creates significant barriers to market entry, due to the high levels of capitalization and skilled labor required. The vaccine production process is considered to be complex, requiring precise production methods. Regulatory requirements are strict to ensure that the production process is safe and effective. The vaccine manufacturing process can take months, involving several steps, including cultivation, purification, quality control, and packaging. The demand for vaccines is limited by the fact that a vaccine product may be used only a limited number of times per person. The confluence of these supply and demand factors makes for an inflexible market, which is why there are shortages in the supply of certain vaccines at times.

The Cost of Vaccines

Over the past couple of decades, immunization costs have increased significantly. From 1995 to 2008, the cost of providing all recommended vaccines to children through age 18 increased between \$150 and \$223 per child to \$1,407 per girl or \$1,105 per boy from 1995 to 2008. Two factors are primarily responsible for these increases, including increases in the number of vaccines and their costs. Since 1999, there have been 8 new recommendations for routine vaccine use among children and adolescents. The new human papillomavirus (HPV) vaccine is one of the costliest vaccines on the market today. See Box 3 for more information about the HPV vaccine product.

Box 3: HPV Vaccine

The Advisory Committee on Immunization Practices (ACIP) recommends that young women between 11 and 13 receive the 3-dose HPV vaccine. ¹⁴ Access to this vaccine today in Massachusetts is presently determined by insurance coverage. HPV vaccine is available to VFC-eligible children through the VFC program, yet it is not available to non-VFC eligibles through state funding. A review of the claims data, however, suggests that individual insurers offer this coverage to their members.

HPV vaccine is used to prevent cancers in females and other conditions in females and males. The manufacturer's price runs about \$130 per dose, or about \$390 for the 3-dose series. At the CDC-negotiated price, the series would run about \$300. For the sake of contrast, the cost of the Tdap vaccine, used to prevent tetanus and diphtheria toxoids and acellular pertussis for adolescents, runs about \$37 per dose, or \$27 at the CDC-negotiated price.

Two manufacturers currently produce the Quadrivalent Human Papillomavirus vaccine. The HPV 4 vaccine is manufactured by Merck. The HPV 2 vaccine is manufactured by GlaxoSmithKline, with differences in recommended ages and the number of types covered by the vaccine.

The HPV vaccine is a good example of the cost of bringing new vaccines to market.¹⁵ According to Merck, the manufacturer of Gardasil, it took over 20 years to develop the vaccine and it is complex to manufacture. The other reason why HPV vaccine is expensive is because of the benefits that Merck estimates that HPV will yield for society. Merck estimates that "HPV-related diseases cost the U.S. health-care system about \$5 billion every year, and we took that into consideration."

Discount Pricing

Under the Omnibus Reconciliation Act of 1993 (OBRA '93), the Congress established the Vaccine for Children (VFC) program for the purpose of improving the availability of vaccines nationwide. OBRA '93 established the VFC program for the distribution of pediatric vaccine to provide publicly-

purchased vaccines to VFC-eligible children to both public and private providers by adding Section 1928 to the Social Security Act (SSA).

Among the many provisions included in Section 1928 of the SSA, the Congress provided the CDC with the authority to negotiate federal contracts with vaccine manufacturers for the purchase of vaccines at discount. The CDC buys VFC-funded vaccines under federal contracts with manufacturers at a discount and distributes them to grantees. Grantees may include state health departments and certain local and territorial public health agencies, which, in turn, distribute the vaccines at no charge to private physicians' offices and public health clinics that are registered as VFC providers for VFC-eligible children. Children who are eligible for VFC vaccines are entitled to receive pediatric vaccines that are recommended by the Advisory Committee on Immunization Practices.

States may also purchase pediatric vaccines under federal contracts. Section 1928 allows states to purchase vaccines at discount for state-eligible children. State-eligible children are defined under this section as follows: "a child who is within a class of children for which the State is purchasing the vaccine pursuant to subsection (d)(4)(B)." In effect, this allows each state to purchase pediatric vaccines at the negotiated discount price.

According to the CDC, states may purchase pediatric vaccines under the federal contracts with manufacturers of pediatric vaccines with the use of state funds or assessments from health insurers, as long as the vaccines are used for state-eligible children. Historically, Massachusetts has purchased its supply of pediatric vaccines for state-eligible children under these federal contracts established for the VFC program funded through state appropriation.

Discounts from vaccine manufacturers under the VFC program are a key component of the state's overall ability to make pediatric vaccines available to children who do not qualify for the Vaccine for Children (VFC) program.

Based on the "CDC Vaccine Price List," negotiated price discounts can range from a high of 50 percent to a low of 10 percent. The discount on the manufacturer's price per dose tends to be higher for relatively-less expensive vaccines. This is largely the result of the language of Section 1928, which favors the federal government's ability to limit increases in the price per dose for vaccines that were included in federal contracts on May 1, 1993 to the consumer price index (CPI). New pediatric vaccines are not subject to the same CPI cap on increases.

Reimbursement for Immunization

Inadequate reimbursement for immunization has been the focus of a number of reports. In March 2009, the National Vaccine Advisory Committee (NVAC) recommended that healthcare providers receive a uniform vaccine administration fee for providing vaccines to ensure adequate reimbursement. The current system, for example, includes several different fee structures based on insurance coverage. The administrative structure established in 1994 for the VFC program has not been updated since 1994.

Nationally, the American Academy of Pediatricians (AAP) has expressed concern about the adequacy of reimbursement for non-vaccine costs, detailing the financial burden facing health-care providers and its potential to adversely affect access to coverage.¹⁷

In a report by the American Academy of Pediatricians (AAP), the academy suggests that achieving maximum immunization coverage is directly linked to the level of reimbursement for immunization. The AAP indicates that there are two types of costs related to providing immunization coverage: (1) the vaccines; and (2) immunization administration. According to the AAP's business case for provider reimbursement, payers should provide reimbursement for vaccines and all costs that are vaccine related, including the purchase price, the personnel costs for ordering and inventory, the storage costs, the cost of insurance, the waste leading to non payment, and the lost opportunity costs from investing in the vaccines. Reimbursement for immunization administration expenses should include physician work, practice expense, and professional liability insurance expense. The AAP reaches the conclusion that total costs of providing vaccine coverage is about 17-28 percent above the direct vaccine purchase price.

According to the Massachusetts Chapter of the American Academy of Pediatricians (AAP), healthcare providers in Massachusetts including physician offices cite inadequate reimbursement for the costs associated with the supplying syringes, managing storage requirements, paying for overhead and spending time on determining eligibility and managing stock based on eligibility.¹⁸

Health Insurers

Private Health Plans: Survey and Claims Data

The Division's consultants prepared a survey sent to seven fully-insured plans in Massachusetts. All seven plans responded to this survey, including Blue Cross Blue Shield Plans, Fallon Community Health Plan, Harvard Pilgrim Health Care, Neighborhood Health Plan, Tufts Health Plan, Unicare, and United. The responses of the health plans were fairly similar.

- All seven health plans cover immunizations. Most if not all adhere to the policy of providing coverage based on the recommended immunization schedule for children and adults of the Advisory Committee on Immunization Practices (ACIP) of the U.S. Department of Health and Human Services. However, health insurers pay for only those vaccines that are not universally supplied by the state. Appendix 1 provides a summary of spending by both fullyinsured and self-insured health plans.
- Health plans provide immunization coverage for Human papillomavirus (HPV) vaccines that MDPH has not been able to afford to provide to health insurers. Appendix 1 provides a summary of the claims data reviewed and analyzed by the Division's actuarial consultants. This summary reveals that health plans are currently spending significant levels on HPV vaccine for both children and adults. (The rate of coverage was not analyzed for this report.) HPV vaccine is not provided by the state due to state budget constraints, but purchased by health insurers. All of the seven health plans surveyed indicated that they pay administrative

fees for providers for state and non-state supplied vaccines. Most indicated that payment for the vaccine is separate from the payment for the vaccine administration. Some indicated that the costs related to vaccine administration are subsumed in the reimbursement for a general office visit. In summary, however, the information provided by health plans is insufficient to determine how current reimbursement for vaccine administration by the health plans compares to "reasonable and customary" standard included in the proposed bill. Reports from providers suggest that reimbursement for administration from health plans does not cover providers' costs.¹⁹

• Most health plans noted that vaccines are not covered if they are work related or experimental.

MassHealth

MassHealth provides immunization coverage for its membership, but it does not generally pay for the cost of vaccines since they are either covered under the Vaccine for Children (VFC) program or by MDHP. However, MassHealth will pay a provider for certain, privately purchased vaccines if the vaccine is not provided by MDPH, or for certain vaccines that are provided by MDPH in instances when MDPH doesn't purchase an adequate supply. MassHealth pays for the administrative cost of providing coverage. However, vaccination services are often bundled as part of an office visit. The separate administrative fee for administration is \$15.78 per visit, based on the maximum rate set for the VFC program when it was established in 1994.

Federal Activity

Federal Legislation

Over the last couple of years, several pieces of legislation have been introduced in the Congress, including the Influenza Vaccine Security Act, the Medicare Improvement Act of 2007, the Vaccine for Children Act of 2008, the Vaccines for the Uninsured Adult Act of 2008, the Vaccine Shortage Preparedness Act of 2008, the Improved Vaccine Supply Act, and the Attacking Viral Influenza Across Nations Act of 2008.

Focus on Maximum Coverage

There has been much discussion about immunization coverage at the national level. Numerous reports have focused on the financial implications of achieving maximum immunization coverage for the benefit of the public health. All aspects of financing immunization coverage have been examined including: the increasing expense of vaccines, the attending administrative responsibilities on healthcare providers, and the financial barriers to access for children, adolescents and adults alike.

Below is a brief description of the myriad of entities involved and their interests:

The National Immunization Program of the Centers for Disease Control and Prevention (CDC) and its Advisory Committee on Immunization Practices (ACIP) are responsible for recommending the immunization schedules for children, adolescents, and adults in the United States. These schedules are available on line from the CDC.

The National Vaccine Program Office of the U.S. Department of Health and Human Services is responsible for developing the U.S. National Vaccine Plan. This plan includes goals, objectives, and strategies for the nation based on a collaborative effort on the part of the federal government to work with many entities including states.

The 2003 Report of the Institute of Medicine (IOM) of the National Academy of Sciences declares that the "immunization of children and adults against life-threatening diseases represents one of the great triumphs of the public health system in the United States, and one of the best bargains in medicine in terms of cost-effectiveness." In this report, the IOM's Committee on the Evaluation of Vaccine Purchase Financing in the United States released its report on financing vaccines in the 21st century focusing on the problems of the current immunization system in this nation, including the increasing disparities in access to recommended vaccines and increasing cost of immunizations. The IOM's report includes a multi-pronged recommendation to: (1) require that all private and public-insurance plans cover recommended vaccines; (2) establish a government subsidy to reimburse private and public insurers and providers for vaccinations; and (3) create a government voucher, related to the subsidy, for uninsured children and adults to receive immunizations through the provider of choice.

In March 2009, the National Vaccine Advisory Committee (NVAC) released its report that examined the financing of immunization coverage, the financial barriers to coverage, and the policies options to address barriers.²¹ In this report, the Committee recommended the establishment of a uniform vaccine administrative fee for health-care providers, and first-dollar immunization coverage. The report is more extensive than described, here, and contains 24 recommendations in total.

In December 2009, the Institute of Medicine released its review of the National Vaccine Plan (NVP) required by the 1986 National Childhood Vaccine Injury Act.²²

State Activity

The New England States

State immunization programs are fairly strong in New England. Three of the six New England states, including New Hampshire, Rhode Island, and Vermont, all have a universal system of purchasing and distributing pediatric vaccines to children.²³ Connecticut, Maine, and Massachusetts are classified among those states with a universal-select system. Massachusetts is considered a universal-select state, because it does not provide all the routinely-recommended-pediatric vaccines. Massachusetts has not been able to supply the HPV on a universal basis. Exhibit 3 provides an overview of the immunization programs in the New England region, including the supply policy of the state, the results from the 2008-2009 National Immunization Survey (NIS) for children 19-35 months of age, and whether the state has an immunization registry.

The results from the NIS are shown in Exhibit 2 in the columns marked A, B, and C. These results highlight Massachusetts with first-place ranking in New England. Among children 19-35 months, 86 percent of children in Massachusetts have received immunization coverage for their 4-3-3-1

series. That series includes the following vaccines: 4 DTaP, 3 Polio, 1 MMR, and 3 Hib. Exhibit 4 also includes results from the CDC's survey for other series for children 19-35 months.

Exhibit 2 also shows that Massachusetts and New Hampshire are the only two states among New England states without an immunization registry. Outside of New England only the state of Kentucky does not have an immunization registry.

Exhibit 2: New England Immunization Programs

State	Supply Policy ^a	A 4-3-1-3 ^b	B 4-3-1-3-3 ^b	C 4-3-1-3-3-1 ^b	Immunization Registry ^c
Connecticut	Universal Select	73%	73%	70%	Yes
Maine	Universal Select	81%	76%	74%	Yes
Massachusetts	Universal Select	86%	84%	82%	No
New Hampshire	Universal Purchase	85%	85%	81%	No
Rhode Island	Universal Purchase	80%	80%	78%	Yes
Vermont	Universal Purchase	75%	74%	65%	Yes

^a Supply policy, as defined by the Centers for Disease Control and Prevention. Universal Status = supplies all routinely-recommended pediatric vaccines to all public and private VFC-enrolled providers for all children through a combination of federal and state funds. Universal Select = supplies all but a few of the routinely-recommended pediatric vaccines to all children.

State Mandates and Proposals

Across the country, states have introduced legislation to improve their immunization programs by forging stronger relationships with health insurers, health plans and health-care providers. As the cost of purchasing vaccines has grown more expensive, states have turned to health insurers to finance vaccines.

- HPV vaccine: Some states have focused on more traditional methods of expanding insurance coverage by enacting laws to require health plans to cover vaccines. California, Texas, Utah and Washington, for example, all have enacted laws to require health plans to cover HPV vaccine.
- Vaccine Funds: Some states have enacted mandatory assessments on health insurers to fund the non-federal program costs of providing vaccine coverage. New Hampshire and Idaho have both established vaccine funds into which assessments from health insurers

^b 4-3-1-3 = 4 or more doses of DTaP, 3 or more doses of poliovirus vaccine, 1 or more doses of MMR, and 3 or more doses of Hib. 4-3-1-3-3 = 4-3-1-3, plus 3 or more doses of HepB.

^{4-3-1-3-3-1 = 4-3-1-3-3}, plus 1 or more doses of varicella vaccine.

^c Immunization Registry = Yes, if the state has an immunization registry.

flow. New Hampshire has the New Hampshire Vaccine Association (NHVA). Idaho has the Immunization Dedicated Vaccine Fund. Both of these funds collect assessments from self-insured plans and fully-insured plans. See Box 4 for more information about the vaccine funds in Idaho and New Hampshire.

Vermont also passed a law in July 2009 to establish an immunization pilot program. The purpose of the pilot program is twofold: to provide all Vermonters universal access to vaccines, and to reduce the cost at which the state may purchase vaccines. This law was passed in July 2009 and provides authority to establish this pilot program and to assess health insurers.²⁴

Most recently, the state of Washington enacted a law to assess health plans. That law was enacted in March 2010, and was effective May 1, 2010. This law creates the Washington Vaccine Association, and is modeled after the NHVA, with the same intent as New Hampshire to preserve "a seamless system" of providing universal coverage for childhood vaccines.

Finally, Connecticut has also considered legislation to finance the non-federal program costs of providing immunizations by assessing health insurers, but has not yet enacted such a law. The state of Connecticut considered the merits of assessing health insurers to fund vaccines in 2009, but the proposed legislation did not pass.²⁵

• Immunization Registries: Every state in the U.S. has an established immunization registry to track vaccine coverage, except for Kentucky, Massachusetts and New Hampshire.

Box 4: State Vaccine Funds

New Hampshire: New Hampshire currently funds its vaccine program through four available sources: the Vaccine for Children (VFC) program, the Section 317 grant, the general fund, and through assessment fees collected from health insurers by the New Hampshire Vaccine Association (NHVA). The NHVA was established as a not-for-profit organization by the New Hampshire State Legislature in 2002 under the NH Revised Statutes Annotated RSA 126-Q. In 2002/2003, the NHVA began the process of collecting assessments with the first year fee set at \$4.00 per covered life annually. That fee has increased over time to \$23.00 in 2009/2010 to cover all routine pediatric vaccines recommended by the ACIP. Assessments are calculated based upon the calculation of the estimated vaccine cost for the state less federal revenues and other general fund revenue. The assessments collected are used by the NHVA to purchase discounts for health-care providers at discounted federal prices. Cost savings are available to both insured and uninsured populations. Self-insured and fully-funded plans participate fully in this program.

Idaho: In March 2010, the Idaho State Legislature established the Immunization Dedicated Vaccine Fund and Immunization Assessment Board. That law was passed in March 2010.

Methodological Approach

Overview of Approach

The Division engaged a consulting team for this project, including the economics and actuarial firm of Compass Health Analytics, Inc. (Compass) to estimate the financial effects of the passage of S. 2195. Independent consultant Ellen Breslin Davidson of EBD Consulting Services, LLC (EBD) and Tony Dreyfus were hired to write the main report, which included reviewing and evaluating the legislation. Anne Geoghegan, an independent consultant, researched and wrote the piece on the immunization registry. The Division, Compass and EBD worked together to evaluate the likely effects of the proposed bill on existing health insurance.

The following steps were taken to prepare the review and evaluation of S. 2195:

1. Conducted Interviews with Stakeholders.

DHCFP conducted interviews with stakeholders in the Commonwealth to ensure that it was accurately interpreting the proposed change in law, to understand the perceptions about how the law would be interpreted, if enacted, and expectations about its likely impacts. The Division completed interviews with legislative staff of Representative Harriett Stanley, Senator Richard Moore, and Representative Alice Wolf. Meetings were also held with health insurers including Blue Cross Blue Shield of Massachusetts, the Massachusetts Association of Health Plans including representatives of member health plans, Unicare Life & Health, and United Healthcare; and communications with Dr. Susan Lett, Medical Director of the Immunization Program, of the Department of Public Health.

2. Reviewed Literature.

DHCFP reviewed the literature to determine the context of the proposed mandate, including issues relative to the cost of immunization coverage, including federal and state funding streams, medical efficacy, and the federal and state landscape. This research included identification of parameters for estimating the cost impacts of S. 2195.

3. Prepared and Collected Survey Data from the Health Plans.

DHCFP requested that health plans respond to a survey developed by Compass and EBD to determine current coverage policies for vaccines for children and adults.

4. Developed Baseline for Massachusetts.

Mandate: The Division provided claims-level data from the health plans in the Commonwealth, using data from DHCFP's data warehouse, to establish a baseline of costs for vaccines and administration that are currently covered by health plans. This data request was prepared by Compass.

Assessment: The Division, and the Massachusetts Department of Public Health, provided data on the total amount of the pediatric assessments estimated to be paid by health insurers in accordance with the requirements for state fiscal year 2010.

5. Applied Assumptions and Sensitivity Analysis to Methodology.

Mandate: Compass developed model parameters for estimating the mandate from a review of the claims data from the Division to produce an estimate of the marginal premium cost of the proposed mandate. The marginal premium cost estimate was driven by the higher cost of providing coverage due to: (1) providing first-dollar coverage; and (2) paying providers the usual, customary, and reasonable charges, and to any willing provider.

Assessment: Compass also developed model parameters for estimating the assessment based upon an analysis of current funding and an estimate of the allocation of current funding across all health insurers, including MassHealth.

Approach for Determining Medical Efficiacy

M.G.L. c. 3 § 38C (d) requires DHCFP to assess the medical efficacy of mandating the benefit, including the impact of the benefit on the quality of patient care and the health status of the population; and, the results of any research demonstrating the medical efficacy of the treatment and service when compared to alternative treatments or services or not providing the treatment or services. To determine the medical efficacy of S. 2195, DHCFP relied heavily upon the substantial research that has been conducted on the efficacy of vaccines.

Approach for Determining the Fiscal Impact of the Mandate

Legal Requirements

M.G.L. c. 3 § 38C (d) requires DHCFP to assess nine different measures in estimating the fiscal impact of a mandated benefit:

- 1. Financial impact of mandating the benefit, including the extent to which the proposed insurance coverage would increase or decrease the cost of the treatment or the service over the next five years;
- 2. Extent to which the proposed coverage might increase the appropriate or inappropriate use of the treatment or service over the next five years;
- 3. Extent to which the mandated treatment or services might serve as an alternative to a more expensive or less expensive treatment or service;
- 4. Extent to which the insurance coverage may affect the number or types of providers of the mandated treatment or service over the next five years;

- 5. Effects of mandating the benefit on the cost of health care, particularly the premium, administrative expenses and indirect costs of large employers, small employers and non group purchasers;
- 6. Potential benefits and savings to large employers, small employers, employees and non- group purchasers;
- 7. Effect of the proposed mandate on cost shifting between private and public payers of health care coverage;
- 8. Cost to health care consumers of not mandating the benefit in terms of out-of-pocket costs for treatment or delayed treatment; and
- 9. Effect on the overall cost of the health care delivery system in the Commonwealth.

Estimation Process

For more detailed information on the methodological approach used to calculate the impact of S. 2195, refer to the Appendix of this report.

Summary of Findings

Medical Efficacy

Several issues about the efficacy of vaccines bear on the public discussion about changes in the way vaccine delivery is organized and financed. One issue is the great efficacy of vaccines in preventing important, dangerous diseases. A second issue is the concern about vaccine risk that has hindered efforts to assure effective vaccination. A third issue is the appearance of new vaccines that bring substantial benefit but also new costs.

Efficacy of Vaccines in Preventing Dangerous Illnesses

Discussion of changes in the organization and finance of vaccine delivery should be made in light of the profound benefit that society has enjoyed to date from vaccines. While the facts on the benefits of vaccines are well known to some, direct experience of the diseases that vaccines prevent is fading with time, so that vaccine benefits bear some re-examination.

The efficacy of vaccination for a number of important diseases is well established. Vaccination stands with a few other advances in sanitation and medicine that have vastly diminished human suffering from disease. The first development of protection in the nineteenth century against diseases such as rabies and smallpox was followed in the twentieth century by a widening array of vaccines against important diseases such as diphtheria, measles, mumps, rubella, tuberculosis, polio and others.

One powerful way to understand the value of vaccination is by considering the rates of illness and death that Americans experienced before various vaccinations were available. The data below on the incidence of five important diseases are from estimates by the federal Centers for Disease Control and Prevention (CDC).²⁶

For example, the polio virus can cause both acute paralysis and permanent disability or death. Before the polio vaccine, there were 13,000 to 20,000 annual cases in U.S. of paralytic polio.

Measles, one of the most infectious diseases, was very widespread before vaccination, with most Americans contracting the illness at some point in their lives. Measles had an average death rate of approximately three deaths per 1000 cases and 450 deaths per year between 1953 and 1963.

Meningitis caused by the bacterium Haemophilus Influenzae Type b (Hib) was the most common bacterial meningitis in children, killing 600 children per year and leaving many others with deafness, seizures or retardation. Since the 1987 introduction of the Hib vaccine, deaths from this cause of meningitis have been nearly eliminated.

Pertussis or whooping cough used to affect large numbers of children, with 150,000 to 260,000 cases per year, and up to 9,000 annual pertussis-related deaths. Both Britain and Japan have experienced outbreaks due to fallen immunization levels, including 100,000 cases and 36 deaths in the UK in the mid-1970s, and 13,000 cases and 41 deaths in Japan in 1979.

The serious bacterial disease diphtheria frequently causes heart and nerve problems and used to be fatal for 5 to 10 percent of its victims, with greater risk of death in the very young and the elderly. Before the introduction of the diphtheria vaccine, this disease sickened or killed many children in the U.S. In 1921 206,000 cases of illness were recorded and 15,520 deaths. After the vaccine, cases fell significantly and in our time diphtheria is extremely rare.

Concerns about Vaccine Risks

While vaccines have provided enormous health benefits, skepticism about vaccines and resistance to their use are significant. Some of the concerns may stem from healthy public skepticism about the motivations and trustworthiness of the medical, pharmaceutical and public health systems. Some of the concerns also stem from unfounded skepticism about the science behind vaccines. While the scientific evidence is powerfully supportive of vaccines, public knowledge and trust in science and its institutions have limits. Public discussion of vaccine policy must proceed in this context.

The persistent belief that vaccines have caused autism is an important element of anti-vaccine skepticism. Some parents of children with autism have embraced the idea that the vaccine preservative thimerosal, which contains mercury, can trigger autism in susceptible children. Antivaccine groups have formed, and thousands of families have sought compensation from the federal vaccine injury fund. (In March, 2010 federal judges ruled against the claims of 5,000 families in the Omnibus Autism Proceeding.) The scientific community has found the claim that vaccines cause autism unsupported by evidence. But even with the elimination of thimerosal from most vaccines, fears about its dangers have caused some parents to decide against vaccines for their children.²⁷

The increasing number of vaccines currently recommended for children has also made vaccines less popular among parents. As vaccine advocates Offit and Moser explain, "Given that young infants currently receive 14 different vaccines, requiring as many as 5 shots at a single visit and 26 inoculations by 2 years of age, the concern that children might be overwhelmed by too many vaccines is understandable."²⁸ (These authors then systematically counter the many claims of antivaccine advocates and provide references to numerous scientific studies to support vaccine safety and efficacy.)

Reduction in vaccination rates threaten to allow some diseases to resurface. On the one hand, suppression of a communicable disease does not require a 100 percent vaccination rate. A small proportion of unvaccinated people may benefit from "herd immunity," in which a large-enough proportion of vaccinated individuals brings protection to unvaccinated individuals because the disease cannot spread.²⁹ On the other hand, when vaccination rates drop substantially, once-rare diseases can quickly return. According to Offit and Moser, "Recent outbreaks of measles in 15 states, caused by an erosion of herd immunity in communities where parents had chosen not to vaccinate their children, were the largest in the United States since 1996."³⁰

Public discussion about vaccine programs must incorporate scientific opinion while recognizing concerns about vaccine safety. Inevitably new vaccines bring the discomfort of scientific uncertainty into public decisions, for example uncertainty about the severity of new flus and the effectiveness

and safety of new vaccines to counter them. But in the case of many established vaccines the science in favor is unusually strong. Public discussion should focus on how best to assure adequate use of extremely valuable health-protection measures.

Efficacy of New Vaccines

The vaccine for human papillomavirus (HPV) brings an important new tool to the vaccines available in preventive medicine. HPV is an extremely prevalent virus among sexually active adolescents and adults, with over half of sexually active adults being infected at some point in their lives. Infections by most types of HPV produce no symptoms and are eliminated by the body's immune system. Some HPV types lead to genital warts. A small proportion of HPV infections, however, can lead to cervical cancer, which is dangerous and sometimes fatal. As a result, the vaccines against HPV can prevent a significant number of deaths and are recommended for adolescent girls.

The efficacy of HPV vaccines has recently been examined by several groups. Bonanni and colleagues found that the efficacy of these vaccines "has proven excellent in several... trials involving tens of thousand women." Medeiros and colleagues systematically reviewed the controlled experiments where HPV vaccines were compared with placebos for efficacy and safety. The six studies they analyzed included 47,236 women. They found that the vaccines "can prevent HPV infection in women aged 9 to 26 years not previously infected with the HPV subtypes covered by the vaccines." Brisson and colleagues have examined efforts evaluate the cost-effectiveness of vaccination and found that their results consistently show that "(1) vaccinating young girls against HPV is likely to be cost- effective; (2) vaccinating boys will most likely not be cost- effective in countries that can reach high coverage rates in girls…"

Calculations done in the Netherlands (2008 population of 16 million) give a vivid sense of how the HPV vaccines could save lives among a population two to three times larger than that of Massachusetts. Westra and colleagues examined analyses of cost-effectiveness of HPV vaccination and found that vaccinating all 12-year-old girls "may ultimately prevent per year 217-421 cases of cervical cancer and 93-173 deaths caused by this disease in the Netherlands." These Dutch researchers found vaccination cost-effective and estimate that "about 1000 girls must be vaccinated to prevent 1 death." They add that "The actual health benefits gained by HPV vaccination are strongly dependent on vaccination coverage. It is therefore important that this remains high (85-100%)." 35

Another important piece of progress in vaccines comes with the development of a vaccination for shingles or Herpes zoster. Shingles are usually a painful skin eruption that is most common among older adults and is a reactivation of chickenpox decades after the initial infection. It will affect up to one third of the population at some point in their lives. A small proportion of people with shingles suffer chronic debilitating pain or painful or dangerous involvement of the eye.³⁶ Usual treatment could shorten the course or lessen the symptoms but until recently there had been no preventive treatment. The new Herpes zoster vaccine appears to be an effective tool for preventing Herpes zoster among people age 60 and older.³⁷ The Shingles Prevention Study, a large placebo-controlled clinical trial, showed large reductions in herpes zoster illness and chronic pain without significant side effects.³⁸

Financial Impact of Mandate

The following questions about the financial impact of the mandate were answered in the context of the vaccine mandate applying to fully-insured health plans. It is expected that S. 2195 would not apply to the self-insured plans, since these plans are exempt under the federal ERISA law. However the assessment would apply to self-insured plans.

- 1. The Division is required to assess the extent to which the proposed coverage would increase or decrease the cost of the treatment or the service over the next five years.
 - Based on a narrow interpretation of this question, should S. 2195 become law, the cost of immunization coverage would increase above current costs to health plans in response to the bill's language around providing members with first-dollar coverage and paying any willing provider 100 percent of reasonable charges for vaccines and costs for administration.
 - A broader interpretation of this question might also consider the potential for savings to health insurers from including HPV in the federal procurement process and discount pricing and the potential for cost avoidance from vaccine waste resulting from a childhood immunization registry.
- 2. DHCFP is required to assess the extent to which the proposed coverage might increase the appropriate or inappropriate use of the treatment or service over the next five years.
 - Should S. 2195 become law, the proposed coverage might lead to an increase in the rate of vaccination, particularly among adults, over the next five year by eliminating cost-sharing requirements for members. However, measured against the full scope of vaccines covered by this bill, any increase in costs to insurers or the health care system due to this increased utilization is probably small due to current high rates of coverage.
 - It is also important to note that any increase in the rate of vaccination for health plans could likely be offset by a lower incidence of vaccine preventable diseases and a reduction in direct medical costs to treat their members.
 - Other provisions in the bill would reinforce more appropriate use of vaccines. Purchasing vaccines through a fund would very likely lead to better coordination of immunization coverage. The creation of an Immunization Registry would also serve to track and coordinate vaccine coverage among health-care providers, with the potential to reduce waste and duplication, and administrative burden for providers.
- 3. DHCFP is required to assess the extent to which the mandated treatment or services might serve as an alternative to a more expensive or less expensive treatment or service.
 - Vaccine coverage lowers the incidence of vaccine-preventable diseases, which lowers health-care costs. As such, the mandated treatment would serve as an alternative to getting the disease and requiring more expensive treatment or services. According to the American Task Force on Immunizations, "vaccines are the most cost-effective and life-saving interventions of modern medicine." According to one study, the set of routinely-recommended child and adolescent vaccines prior to 2000 saves the country approximately \$10 billion in direct costs and \$43 billion in societal costs annually.³⁹

- 4. DHCFP is required to assess the extent to which the insurance coverage may affect the number or types of providers of the mandated treatment or service over the next five years. There is no evidence to indicate that proposed legislation would increase the number or types of providers of the mandated treatment or service over the next five years.
- 5. DHCFP is required to assess the effects of mandating the benefit on the cost of health care, particularly the premium, administrative expenses and indirect costs of large employers, small employers and non-group purchasers. The Division estimated the fiscal impact of the bill (see Appendix 1) relative to the effect S. 2195 would have on health insurers. Estimated impacts of S. 2195 on Massachusetts health care premiums for fully-insured products were calculated assuming that the five-year average premium (2011-2015) for a fully-insured member is \$498 on a per member per month basis. Low, middle and high scenarios used varying assumptions of costs and use.

Vaccine Mandate: The five-year impact results are displayed in Exhibit 3. The results include three sets of estimates based on low, medium, and high impact scenarios. The five-year total for these three scenarios resulted in estimated increased total spending (including both claims spending and administrative expenses) of \$58.6, \$97.6, and \$117.1 million, respectively. These results include fully-insured plans under the Group Insurance Commission (GIC).

Exhibit 3: Estimated Cost Impact of S.2195 on Fully-Insured Health Care Premiums (2011-2015)

Plan Category	2011	2012	2013	2014	2015	All 5 Years
Fully-Insured Enrollment	2,356,000	2,354,000	2,352,000	2,351,000	2,350,000	
	2,330,000	2,334,000	2,332,000	2,331,000	2,330,000	_
Low Scenario (Millions)						
Annual Impact Claims	\$9,735	\$10,007	\$10,288	\$10,594	\$10,909	\$51,533
Annual Impact Administration	\$1,327	\$1,365	\$1,403	\$1,445	\$1,488	\$7,028
Annual Impact Total	\$11,062	\$11,372	\$11,691	\$12,039	\$12,397	\$58,561
Premium Impact (PMPM)	\$0.39	\$0.40	\$0.41	\$0.43	\$0.44	\$0.41
Middle Scenario						
Annual Impact Claims	\$16,224	\$16,679	\$17,147	17,657	18,182	85,889
Annual Impact Administration	\$2,213	\$2,275	\$ 2,338	\$2,408	\$2,480	\$11,714
Annual Impact Total	\$18,437	\$18,954	\$19,485	\$20,065	\$20,662	\$97,603
Premium Impact (PMPM)	\$0.65	\$0.67	\$0.69	\$0.71	\$0.73	\$0.69
High Scenario						
Annual Impact Claims	\$19,469	\$20,015	\$20,576	\$21,188	\$21,819	\$103,067
Annual Impact Administration	\$2,655	\$2,729	\$2,806	\$2,890	\$2,975	\$14,055
Annual Impact Total	\$22,124	\$22,744	\$23,382	\$24,078	\$24,794	\$117,122
Premium Impact (PMPM)	\$0.78	\$0.81	\$0.83	\$0.85	\$0.88	\$0.83

- 6. DHCFP is required to assess the potential benefits and savings to large and small employers, employees, and non-group purchasers.
 - It is unlikely that this mandate would produce a substantial increase in the benefits to employers. The benefits are societal. In that sense, the employers would benefit from a healthier and more productive pool of employees in the long run.
- 7. DHCFP is required to assess the effect of the proposed mandate on cost shifting between private and public payers of heath care coverage.
 - As written, S. 2195 applies the mandate to all health insurers, including fully-insured carriers and self-insured plans, the Group Insurance Commission and MassHealth. The Division expects two types of shifts in costs as a result of the mandate: (1) a shift in costs from self pay to the insurer; and (2) a shift in costs from private providers to private carriers.
 - The big shift between private and public payers of health-care coverage from the state's general fund to health insurers comes from the assessment. That shift occurred through the state's fiscal year 2010 budget, but this provision is due to expire at the conclusion of state fiscal year 2010. That expiration date represents much of the impetus behind consideration of this legislation.
- 8. DHCFP is required to assess the cost to health care consumers of not mandating the benefit in terms of out-of-pocket costs for treatment or delayed treatment.
 - Should the proposed mandate become law, health care consumers would experience lower outof-pocket costs. This would affect the underinsured more than any other group.
- 9. DHCFP is required to assess the effects on the overall cost of the health care delivery system in the Commonwealth.

The cost of the health-care delivery system in the Commonwealth will increase as a result of the proposed vaccine mandate and the requirement that health plans pay 100 percent of the reasonable and customary charges for vaccines and costs for administering vaccines, as well as provide first-dollar coverage to recipients of vaccines. Overall health-care costs might also increase should immunization rates improve. However, Massachusetts already has an excellent rate of immunization across the population, leaving less room for improvement.

However, it is important to note that DHCFP's analysis of the increase in the cost of the health-care delivery for health insurers above current costs assumes that, even in the absence of passage of the proposed bill, health insurers would continue to experience cost avoidance from the following sources: (1) cost avoidance from utilizing the federal procurement process, and corresponding lower costs for vaccines; (2) cost avoidance from a lowered administrative burden for providers and health plans as a result of a universal pediatric vaccine program; and (3) cost avoidance from a reduction in health-care costs related to acquiring the very diseases that vaccines prevent and from improved tracking through the Immunization Registry. However, these are clearly benefits that lower the cost to the health-care delivery system presently. DHCFP's analysis also does not consider the potential for future savings to the health care delivery system from CDC pricing for HPV, since HPV is not currently calculated as part of the assessment.

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Publication Number: 10-216-HCF-01 Authorized by Ellen Bickelman, State Purchasing Agent

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Appendix

Actuarial Assessment of
Massachusetts Senate Bill 2195 (House 3453)
An Act Relative to Establishing
the Massachusetts Childhood Vaccine Program
and the Massachusetts Immunization Registry

Actuarial Assessment of Senate Bill 2195 (House 3453): An Act Relative to Establishing the Massachusetts Childhood Vaccine Program and the Massachusetts Immunization Registry

Prepared for

Commonwealth of Massachusetts Division of Health Care Finance and Policy

Prepared by

Compass Health Analytics, Inc.

June 11, 2010



Actuarial Assessment of Senate Bill 2195 (House 3453): An Act Relative to Establishing the Massachusetts Childhood Vaccine Program and the Massachusetts Immunization Registry

Table of Contents

E	xecutive Summary	i
1.	Introduction	1
2.	Interpretation of S.B. 2195	2
	2.1 Insurance entities subject to S.B. 2195	2
	2.2 Vaccination mandate provisions and current law	4
	2.3 Childhood Vaccination Program and the child immunization assessment	5
3.	Factors Affecting the Analysis	7
	3.1 Vaccination mandate issues	7
	3.2 Child immunization fee assessment issues	12
	3.3 Time-dependent factors	14
4 .	Methodology	15
	4.1 Analysis steps	15
	4.2 Data sources	15
5.	Analysis	16
	5.1 Estimating the insured population affected by the mandate	16
	5.2 Current claim costs for vaccinations and administration	17
	5.3 Changes in vaccination costs due to S.B.2195 mandate	18
	5.4 Increase in covered costs to be paid by health insurers	19
	5.5 Effect of the mandate on health insurance premiums	21
	5.6 Effect of the assessment on health insurance premiums	23
Co	onclusion	25
Αį	ppendices	27
	Appendix A: Detail of Claim Data	28
	Appendix B: Estimated Vaccine Cost and Units by Type and Funding Source	29



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Actuarial Assessment of Senate Bill 2195 (House 3453): An Act Relative to Establishing the Massachusetts Childhood Vaccine Program and the Massachusetts Immunization Registry

EXECUTIVE SUMMARY

Senate Bill 2195, before the 2009-2010 session of the Massachusetts Legislature, modifies the manner in which vaccines and vaccinations are financed and paid for in the Commonwealth, including mandating insurance coverage for vaccinations. The Massachusetts Division of Health Care Finance and Policy (the Division) engaged Compass Health Analytics, Inc. to provide an actuarial estimate of the effect that enactment of the bill would have on the cost of health care insurance in Massachusetts.

Background

Most bills referred to the Division under the statute enabling mandate review¹ are focused on mandating a benefit for coverage by fully-insured commercial insurance policies regulated by the Commonwealth. S.B. 2195 includes provisions that would add a mandate for fully-insured policies to cover vaccinations for children and adults. However the bill contains language that also directs self-insured commercial plans and the state Medicaid program to cover vaccines. It can be assumed, however, that self-insured plans would not be subject to the mandate under current federal law. In addition to these benefit mandate provisions, the bill modifies the current method of financing payment for childhood vaccines by authorizing an assessment upon the same payer categories (fully-insured commercial, self-insured commercial, and Medicaid).

This analysis focuses on producing an estimate of the impact of both the mandate and the assessment on fully-insured commercial plan premium levels (consistent with typical analyses under the mandate review statute). Determining whether the Legislature has the authority to impose a mandate and/or assessment on self-insured plans is beyond the

¹ M.G.L. c. 3, §38C (a).

scope of this report, but taking the bill as written, this report provides information about the dollar magnitudes associated with the mandate and assessment for the self-insured plans. A similar rough sample estimate of the effect of the assessment is provided for the Medicaid program. Since the bill's language delegates determination of many of the specifics regarding the assessment to rulemaking by executive branch agencies, precise estimation is not possible and the information provided is intended only to provide approximate magnitudes.

Analysis

The analysis is divided into two parts: estimating the impact of the mandate, and estimating the impact of the assessment. Compass estimated the impact of the mandate by taking the following steps:

- Measure the degree to which insurers are currently paying claims for vaccines and their administration, drawing upon the Division's health care claims database.
- Determine the additional amounts to be paid to comply with S.B. 2195's mandate to pay usual, customary, and reasonable charges, with no cost-sharing, and to any willing provider.

The impact of the assessment was calculated by the following steps:

- Determine the approximate size of the assessment described by the bill, by referencing and adjusting the current funding the assessment would replace.
- Define and apply an approximate allocation basis for the assessment to the various insurance entities described in the bill (fully-insured commercial, self-insured commercial, Medicaid).

The estimate of the total impact on each payer category incorporates the assessment component and the mandate component. For commercial payers, Compass added adjustments for administrative expense and risk/profit estimates to arrive at the total cost to premium payers.

Summary results

Massachusetts commercial insurers, under both fully-insured products subject to state mandates and self-insured products not subject to mandates, already pay for substantial amounts of vaccinations, as illustrated by the summary of claim data in table ES-1.

Table ES-1: 2008 Vaccine and Administration Cost per Member per Month

		Admin Paid		Vaccine Paid	Admin Units	Vaccine Units
Fully Insured Adult (<65) Child 0-19	\$ \$	0.32 2.11	\$ \$	0.82 2.61	0.02 0.13	0.02 0.06
Self Insured Adult (<65) Child 0-19	\$ \$	0.39 2.51	\$ \$	0.98 3.22	0.02 0.13	0.02 0.06

The primary focus of our work is on the impact to premiums for fully-insured private plans, over and above these amounts already paid. The average net premium cost of S.B. 2195 over the next five years for those plans ranges from approximately \$34 million to \$45 million per year. The estimated mean PMPM cost over five years is \$1.19 to \$1.60. We estimate that S.B.2195 would increase fully-insured premiums by 0.24 to 0.32 percent.

Table ES-2 below summarizes the effect on costs for all plan types, averaged over five years and reflecting the midpoint of estimate ranges. Should changes in the bill, or subsequent rule-making, modify the set of plans subject to the assessment, or specify an allocation method different than the sample method used here, the assessed amounts will change. For example, should it be determined that Medicaid/MassHealth is not subject to the assessment, its share would be reallocated among the other assessment payers. The body of the analysis presents more detail, and presents assumptions about the bill's language and provider billing practices on which these estimates rely.

Table ES-2: Estimated Incremental Impact of Mandate and Assessment (000's)

Plan Category	Mandate	Ass	sessment	Total	Premium Impact	PMPM Impact
Fully-Insured	\$ 17,178	\$	19,260	\$ 36,438	\$ 41,407	\$ 1.47
Self-Insured	\$ 11,161	\$	17,400	\$ 28,561	\$ 30,877	\$ 1.23
Total Commercial	\$ 28,339	\$	36,660	\$ 64,999	\$ 72,284	
Medicaid/MassHealth	-	\$	15,800			

These costs should be considered in the context of potential societal savings outside the medical care system of an effective vaccination program, including those realized in education and in workplace productivity, although the primary impact of the law will be to modify the sources of financing for the existing extensive vaccination program.

Actuarial Assessment of Senate Bill 2195 (House 3453): An Act Relative to Establishing the Massachusetts Childhood Vaccine Program and the Massachusetts Immunization Registry

1. Introduction

Senate Bill 2195, before the 2009-2010 Session of the Massachusetts legislature, establishes funding for the Massachusetts Childhood Vaccine Program (CVP) and mandates insurance coverage for vaccinations for children and adults. The Massachusetts Division of Health Care Finance and Policy (the Division) engaged Compass Health Analytics, Inc. to provide an actuarial estimate of the effect that enactment of the bill would have on the cost of health care insurance.

S.B. 2195 is not typical of the mandate bills the Division usually evaluates, which most often simply require coverage for a particular set of services or diagnoses. Instead, it has two major financial components: the mandate requiring coverage for vaccinations, and an assessment on insurers as the mechanism for state funding for the CVP. We will lay out our assumptions and analysis for each in this document.²

Assessing the cost impact entails analyzing the incremental effect of the bill on spending for those insurance plans subject to the proposed law. This in turn requires estimating spending under the provisions of the proposed law and comparing that projection to spending under current statutes and current benefit plans, for the relevant services.

Section 2 of this analysis outlines the provisions of the bill. Section 3 discusses important considerations in translating S.B. 2195's language into estimates of its

June, 2010 Compass
Health Analytics Page 1

²While the assessment portion of the bill will affect premium payers, it is not a "mandated health benefit" under the mandate review statute. M.G.L. c. 3, §38C (a) provides that a "mandated health benefit proposal is one that mandates health insurance coverage for specific health services, specific diseases or certain providers of health care services". Nonetheless its impact will be part of the scope of this analysis.

incremental impact on health care costs. Section 4 describes the basic methodology used for the calculations in Section 5, which steps through analysis and its results.

2. Interpretation of S.B. 2195

Section 1 of S.B. 2195 establishes a new chapter of the General Laws (c. 118I) governing the Childhood Vaccine Program (CVP), including the operations and funding of the Vaccine Purchase Trust Fund to support childhood vaccination, and mandating vaccinations for children and adults. The bill provides that resources for the trust fund will come from health insurers, in the form of a child immunization fee determined and assessed by the Division of Health Care Finance and Policy.

Section 2 of the bill amends G.L. chapter 111, directing the Department of Public Health to create the vaccination immunization registry, funded by the trust fund. The Division's report, to which this actuarial analysis is attached, contains more detailed descriptions of the provisions of sections 1 and 2. This analysis will focus on the financial implications of the mandate and assessment.

2.1 Insurance entities subject to S.B. 2195

S.B. 2195 states that health insurers, as defined in the bill, are both subject to the mandate and assessed the child immunization fee. The bill defines health insurers as:

- Surcharge payors as defined in section 34 of chapter 118G of the General Laws, namely any entity that pays for health care services provided at acute care hospitals and ambulatory surgical centers. The group includes essentially all commercial payors, but excludes Medicaid and Medicare
- Plans for state employees and participating county and local governments (G.L. chapters 32A and 32B)
- Medicaid, including Medicaid managed care organizations
- Any other medical assistance program operated by a governmental unit for persons categorically eligible for such program

In summary, "health insurer" includes private fully- and self-insured health insurance plans, Qualifying Student Health Insurance Plans (i.e., QSHIPs, as surcharge payors), MassHealth, CommCare, and any other medical assistance program operated by the state government. It excludes plans offering solely vision or dental care.

In particular, note the definition includes self-insured plans (i.e., the employer policy holder retains the risk for medical expenditures and uses the insurer to provide administrative functions) because they are surcharge payors.³ Typically, self-insured plans are governed by ERISA and subject to federal law, and not to state-level mandates. However, for the purposes of this analysis, we will estimate the impact of the mandate provision of the bill on self-insured plans – should that be applicable – and present them separately. The mandate provision does apply to GIC self-insured plans, since the Legislature can direct the commissioners of the GIC to follow the mandate.

In contrast to the requirement to cover vaccinations, the assessment is not, strictly speaking, a mandate. It is beyond the scope of this analysis to determine whether the state can levy an assessment against self-insured plans. Therefore, for purposes of the analysis we assume the self-insured plans are among the plans to which the assessment is applied.

Medicaid is also part of the bill's definition of health insurer, as is "any other medical assistance program operated by a governmental unit for persons categorically eligible for such program". We assume that MassHealth programs that are not strictly Title XIX Medicaid programs (e.g., the Children's Health Insurance Program) fall into this last catch-all. As of the date of this analysis, we understand that Medicaid might still be dropped from the definition; however, this analysis will consider the approximate effect on Medicaid. The program is performing its own evaluation of the impact of S.B. 2195 on its budget.

³ Earlier versions of the bill explicitly included "all self-insured plans to the extent not preempted by federal law" (and any excess loss insurance they might maintain). Since "surcharge payors" includes self-insured plans, we assume removing the explicit reference to self-insured plans was not meant to exclude them entirely.

Finally, the bill explicitly excludes state-regulated Medicare supplement policies, as described in G.L. c. 176K, and does not reach individuals with Medicare coverage and federally-regulated "medigap" policies, as these are not subject to state law.

2.2 Vaccination mandate provisions and current law

Services mandated by S.B. 2195

For the insured population subject to the mandate, S.B. 2195:

- Mandates coverage for routine childhood (i.e., ages 18 and under) immunizations⁴ for all residents⁵
- Mandates coverage, for residents 19 years and over, for immunizations recommended by the US DHHS Advisory Committee on Immunization Practices
- Mandates coverage for administering the vaccines
- Exempts the mandated coverage from any copay, coinsurance, deductible, or dollar limit
- Requires insurers to pay providers 100% of "reasonable and customary" charges for the services, including the cost of vaccines (excluding vaccines provided by the state) and the administration costs
- Requires an insurer to reimburse any provider who administers covered immunizations in any setting, even if the provider is not a provider participating in the insurer's network

Existing vaccination benefit mandate

Under current law, insurers offering fully-insured health insurance plans (plans under which the insurance company bears the risk of medical expense) must cover preventative

June, 2010 Compas

COMPASS Page 4

⁴ Routine immunizations include as a minimum those recommended by: (1) the federal Vaccines for Children Program and (2) the US DHHS Advisory Committee on Immunization Practices.

⁵ The mandate provision of S.B. 2195 can effectively reach only insurance plans regulated by (issued in) Massachusetts, and Massachusetts residents who commute to other states and are insured in those states are generally not included in the membership of insurers from whom we have data.

care, including appropriate immunizations, for children from birth to age six.⁶ However, the law offers no guidelines for what vaccines must be covered. It does not limit cost sharing (copays, deductible, etc), establish any rate standards (such as "reasonable and customary"), or require insurers to reimburse out-of-network providers.⁷

The existing mandates do not require coverage for members of GIC plans. Nor do existing mandate statutes reach non-GIC self-insured plans.

Section 5 of this analysis will make clear that both fully-insured and self-insured plans currently pay for vaccinations beyond existing mandate requirements.

2.3 Childhood Vaccination Program and the child immunization assessment

Current vaccination program and funding

The Department of Public Health is required to establish a universal immunization program⁸. The Division's report, to which this actuarial analysis is a supplement, describes the purpose and operation of the program in more detail. The program's budget includes state and federal funds, with \$47 million budgeted for childhood vaccines not funded by federal sources for FY 2010.⁹ Through FY 2009, this non-federal funding for childhood vaccination came from the General Fund, but for FY 2010, the Legislature established a one-time assessment on commercial insurers.¹⁰ Under S.B. 2195, the

⁶ G.L. c. 175, § 47C, G.L. c. 176A, § 8B, G.L. c. 176B, § 4C, G.L. c. 176G, § 4.

⁷ Currently, the "any willing provider standard" in Massachusetts is limited to pharmacies; G.L. c. 176D, §3B. An HMO must contract with any pharmacy willing to accept its prices. ⁸ G.L. c. 111, § 24I.

⁹ The FY 2010 vaccine budget is \$124 million with \$50.7 million covered by the state. Of the state total \$46.6 million is for pediatric vaccines and \$4.1 million is for adult vaccines. The adult vaccines funded by the state are general fund money not affected by S.2195. Email from Pejman Talebian, Massachusetts Department of Public Health January 15, 2010. The Department did not provide a breakdown of the state funds by insured status (commercial, Medicaid, uninsured, etc.) of the children served. Note the federal funds making up the balance of the \$124 million supply vaccines for income-eligible people generally not covered under the commercial insurers that are the focus of this analysis.

¹⁰ Chapter 120 of the Acts of 2009, §47, specified a line item of \$52,135,817 for childhood vaccines, and provided that "the costs of purchasing and distributing childhood vaccines for children in this item may be

Division would be responsible for specifying, through regulation, the methodology for assessing the surcharge on payers.¹¹

Vaccines purchased with both federal and state funds are purchased, through programs run by the CDC, at a discount of approximately 40% off the "standard" price. The vaccines are distributed to providers at no charge.

The intent of the program is to provide all recommended childhood vaccines, but due to funding limitations, the time required to implement distribution of new vaccines, or other reasons, the program has not always reached that goal. For example, currently DPH estimates that another \$9.5 million would be needed to distribute the HPV vaccine universally.¹²

MassHealth currently reimburses providers for administering vaccines, but typically does not pay for the vaccines themselves, as vaccines are funded either directly by the federal government in payments to MassHealth or by these DPH programs.¹³

The Childhood Vaccination Program in S.B. 2195

S.B. 2195 establishes the Vaccine Purchase Trust Fund to fund purchase and distribution of vaccines for children, as well as the Massachusetts Immunization Registry. Through regulation, the Division will assess each health insurer, as defined in the bill, a "child

assessed on surcharge payers under section 38 of chapter 118G of the General Laws and may be collected in a manner consistent with said chapter 118G".

¹² Email from Pejman Talebian, Massachusetts Department of Public Health, January 15, 2010.

¹¹ The proposed methodology for the FY 2010 one-time assessment against surcharge payors was apportioned using insurers' payment to hospitals and ambulatory surgical centers. Interview with Division staff, January 8, 2010.

¹³ MassHealth providers are permitted to bill for vaccination services, either indirectly as part of an office visit or directly. Because most providers elect to bill for an office visit, the agency has no useful measure of the current number of vaccinations that are reimbursed. Memo "Implications of S. 2195 on the MassHealth Program Relative to Vaccine Administration", MassHealth, January 2010.

immunization fee". The methodology for apportioning the total amount of the assessment among health insurers is left to the Division and the regulatory process.¹⁴

3. FACTORS AFFECTING THE ANALYSIS

Several issues arise in translating the provisions of S.B. 2195 discussed above in Section 2 into an analysis of incremental cost.

3.1 Vaccination mandate issues

In general Massachusetts has a high vaccination rate, ¹⁵ and insurer survey responses confirm wide coverage for vaccinations and administration. And while passage of S.B. 2195 will induce shifting among sources for vaccine funding, we expect changes to overall utilization to be modest at most. Nonetheless, we will consider the following factors that might affect the number and/or cost of vaccinations delivered.

Required vaccinations and administration

S.B. 2195 specifies standards for identifying covered vaccinations for adults and children. Survey responses from carriers indicate they cover a wide range of vaccinations that the member's provider determines as medically necessary, along with administration for vaccines both covered by the plans and provided by the state. For example, Blue Cross Blue Shield of Massachusetts, the largest carrier, covers vaccinations (and associated administration) in accordance with the recommendations of national bodies such as the Advisory Council for Immunization Practices, the same standard as in the bill. We expect this factor to contribute little to the incremental cost of the mandate.

¹⁴ The plans targeted for assessment include MassHealth. We do not address here whether MassHealth's share of the assessment would be eligible for federal financial participation (FFP). MassHealth notes the assessment may fall within the definition of a healthcare-related tax. All such taxes must be implemented in accordance with 42 CFR 433.68 to avoid a risk of FFP disallowance.

¹⁵ Massachusetts Department of Public Health, "Summary of Immunization Level Surveys 2008-2009". Also see the Kaiser Family Foundation health facts, showing the Massachusetts childhood vaccination rate at 84%, vs. a national average of 80%. http://www.statehealthfacts.org/profilecat.jsp?rgn=23&cat=2.

Elimination of cost-sharing

Some plans may have cost-sharing provision that apply to vaccinations. For example, most Blue Cross Blue Shield HMO plans provide full coverage for immunizations (including administration and the vaccine) but its PPO plans typically require an office visit copayment for immunizations. To get a rough approximation of the amount of cost-sharing, we can look at the Division's claim data, which shows that for fully-insured plans for members under 65 (to eliminate Medicare members) the difference between the allowed amount (the amount the plan recognizes should be paid for the service) and the amount actually paid by the plan to providers is about 11%. Some other factors, including members with multiple sources of insurance, might contribute to this number, but it provides at least an anchor for a range of estimates.

Besides making the insurer responsible for the cost-sharing amount¹⁷, the elimination of cost-sharing might induce members – who have avoided vaccinations to avoid the associated copayments – to seek them, raising the number of vaccinations received (possibly for both state-funded and insurer-funded vaccines). However, as noted above, we do not assume the bill will drive much new utilization.

Reasonable and customary charges

S.B. 2195 requires insurers to pay 100% of reasonable and customary fees for vaccines (not provided for free by the government) and for administration. If this provision restricts insurers' ability to negotiate contracts with providers that set rates below the stated level, it could result in higher fees. Again, the Division's claim data provides some insight into the magnitude of this effect. In the data for fully-insured plans, the billed amount is some 40% higher than the allowed amount. To the extent the billed amounts represent reasonable and customary fees and allowed amounts reflect rates set below that

¹⁷ In theory if a vaccination does not count against a member's deductible, another service will, so the net effect on cost-sharing is probably more correctly limited to eliminating copayments, which is another reason we will take the values from the claim data as only contributing to a range of estimates.



¹⁶ See Appendix A. The difference between allowed and paid amounts is much smaller for self-insured plans.

level, the difference may provide some insight into the potential magnitude of this effect. In some cases, however, the billed amount may reflect charges above reasonable and customary levels. Therefore for purposes of this analysis, we will assume that this provision will increase the costs of vaccines and administrations covered by insurers, using the difference between billed and allowed amount as an upper bound for our range of estimates.

We cannot determine whether any such fee increase would override existing contracts and take effect immediately or take effect gradually as contracts come up for renewal, but we will assume any fee increase occurs at once.

MassHealth does not pay for most vaccines, and as noted, while it covers administration, it does not generally pay a separate fee for administration due to provider billing practices. MassHealth managers have not prepared an estimate of the effect of this provision on the program's costs for vaccine administration. But to the extent administration is billed separately, the managers expect the reasonable and customary rate would be substantially more than current MassHealth rate. However, in this analysis we do not have information sufficient to estimate this amount (and our primary focus is on private payers).

Reimbursement for administration

S.B. 2195 provides that insurers shall pay "any reasonable and customary costs associated with the administration of the vaccines". To estimate the impact of the mandate on administration costs we measure administration reimbursements in the Division's claim data and assume it will be affected by the elimination of cost sharing and the requirement for reimbursement of reasonable and customary charges discussed above. However, we recognize that vaccine administration services are often buried in office visit charges.

Page 9

June, 2010 COMPASS

¹⁸ Memo "Implications of S. 2195 on the MassHealth Program Relative to Vaccine Administration", MassHealth, January 2010. Any estimate of MassHealth administration fees is complicated by providers' preferences for administering the vaccines under office visit procedure codes.

At least one carrier, in its response to the Division's survey about S.B. 2195, said that when a provider bills a minimal office visit procedure (CPT code 99211) in addition to a vaccine administration procedure code on the same day, the carrier denies the minimal office visit. We have no evidence that this denial practice is widespread, but if it were, and if S.B. 2195 were also interpreted to require carriers to pay for administration procedures that occur on the same data as office visits, the impact of S.B. 2195 would be considerably greater. For this analysis we will assume that providers will follow roughly the same billing practices as they do today, and assume the number of administration procedures remains roughly the same (though administration unit costs will increase due to the factors already discussed).

This issue applies as well to MassHealth/Medicaid. MassHealth reports that most providers bill vaccine administration under an office visit. We do not expect that S.B. 2195 would change this practice unless the bill were interpreted to direct MassHealth to allow providers to bill the administration procedure in addition to the office visit.

"Any willing provider" standard

S.B. 2195 requires an insurer to pay any willing provider of vaccines in any setting, even providers not within the insurer's network.

Insurers' administrative costs would probably increase somewhat during a transition period as they establish new procedures to deal with out-of-network providers who vaccinate members. And beyond administrative cost, insurer survey responses indicate

¹⁹ A rough approximation might be derived from the data in Appendix B. Assuming doses and units in the claim data are compatible and Medicaid administration units are negligible, providers administered 3.5 million doses, but claimed only 2.5 million administration procedure code units, meaning some million administration procedures were not claimed or were buried in office visits. If providers were not submitting these procedures because they might be denied and if S.B. 2195 requires carriers to cover them, then, at an average cost of close to \$20 per unit (based on the Division's data), it would add up to another \$20 million to the impact of S.B. 2195 on commercial plans (fully- and self-insured). This is on top of the estimate due to other factors, quantified in section 5 of this analysis.

that some plans have had to deny claims by members for flu shots at non-approved providers. If the plans can no longer deny these claims, a small increase in reimbursed claims might result; however we have no information on which to base an estimate, and any estimated value would likely be much smaller than the other factors we have discussed.

If S.B. 2195 passes, MassHealth might find itself caught in a conflict between state and federal law. Federal law requires Medicaid programs to pay only providers with whom the program has a written provider agreement.²⁰ For this analysis we will assume no increase in MassHealth vaccine administration expenditures due to this provision.

HPV costs

The costs for HPV vaccine make up a large portion of the total insurers spend on vaccines. For example in calendar year 2008, the Division's claim data reflected \$23 million in reimbursements to providers for HPV vaccine, out of \$52 million for all vaccines. And for the fiscal year ending in June 2008, the Division's claim data showed an even higher amount of \$29 million, out of \$57 million.

When we adjust the \$23 million in 2008 HPV costs by expanding it to the full commercially-insured population, the total is closer to \$34 million. This is higher than the \$9.5 million DPH estimates would be needed to support HPV vaccines through the Vaccine Purchase Trust Fund. At least three factors contribute to this difference:

- The HPV vaccine is recommended for girls/women until ages 11 to 26; the Division's claim data include vaccines for adults. The Trust Fund provides vaccines only for children. Of the \$34 million, about \$21 million was paid for children.
- The Division's claim data (even though they are paid amounts net of costsharing) do not reflect discounts available to DPH.
- The HPV vaccine was approved by the FDA in mid-2006. 2007 and 2008 are probably part of a transition period, and the vaccination rate reflects not only

²⁰ Memo "Implications of S. 2195 on the MassHealth Program Relative to Vaccine Administration", MassHealth, January 2010.

the ongoing vaccination rate, but vaccines for some of the backlog of girls and women previously unvaccinated. We do not have a firm estimate for how long this elevated rate would continue, although the decline from fiscal year 2008 to calendar year 2008, and the limited size of the pool of females ages 11 to 26 suggests a decline is likely.

This report uses claim data to establish a base for vaccine expenditures against which we apply percentage increases due to the mandated limits on cost sharing and potentially higher charges discussed above. However, the presence of a transient start-up effect and the finite eligibility pool makes it likely that the amount spent on HPV vaccine will decline into the 2011 to 2015 period.

We do not have data (including the expected vaccination rate in Massachusetts²¹ and how quickly the backlog will be processed) upon which to base an estimate of the decline. However if we assume, for example, that the vaccination rate would decline to half the 2008 rate, we would adjust the vaccine portion of the 2008 base down by approximately 21 percent (50% of 42%, the proportion of HPV to total vaccines). And since vaccines were close to 60 percent of the total amount paid (vaccine plus administration), the total will drop by 21 percent of 60 percent, or approximately 15 percent, and slightly more if administration costs are also affected. Thus in this example, the cost of the mandate portion of S.B. 2195 in the 2001-2015 period, after adjustments for factors that increase costs, would also be approximately 15 percent lower.

3.2 Child immunization fee assessment issues

As noted in Section 2 of this analysis, S.B. 2195 instructs the Division to assess health insurers, as defined in the bill, for the cost of the Vaccine Purchase Trust Fund. The mechanism for allocating the budget of the trust fund across the pool of insurers is not specified.

Compas Health Analytic

²¹ Studies based on the short history of the HPV vaccine show national rates varying from 10 percent for adults to 37 percent for girls ages 13 to 17. See, e.g.,

http://www.cdc.gov/vaccines/stats-surv/nisteen/data/tables_2008.htm#overall.

Plans assessed under the bill

The primary intent of this analysis is to evaluate the effect of S.B. 2195 on fully-insured premium payers, and the size of the pool of payers clearly affects the impact per premium payer (per member). If all plans in the bill's definition of health insurers pay a share of the trust fund budget, each will pay less than if the budget must be borne by only some of the plans. For purposes of this analysis we will include all the major plans listed as health insurers in the bill, and show the portion allocated to each. Should changes in the bill, or subsequent rule-making, modify the set of plans subject to the assessment, the assessed amounts will change. For example, should it be determined that Medicaid/MassHealth is not subject to the assessment, its share would be reallocated among the other assessment payers.

Apportioning the assessment

S.B. 2195 leaves to the Division the specification of the formula by which health plans will be assessed. Therefore, we cannot know how the assessment will be allocated. For purposes of this analysis, we will assume the allocation will be based on child membership, since the Fund exists primarily to serve children. The Division may choose other allocation approaches, including those based on general membership, surcharge payments, etc., which will produce different allocations, but our example will serve to provide a rough order of magnitude for the assessment and allow the Division and Legislature to gauge its impact.

Applicability of retention to assessment payments

Once each plan's assessment is settled, determining how it will affect premiums will require adding to it any allowed retention for administrative expense and profit. We are assuming the fully-insured plans will apply a 12 percent retention rate. We will assign self-insured plans a 7.5 percent administrative expense rate.

As noted, DPH currently procures vaccines at a substantial discount.²² Assuming the discount remains available to the program, it offers opportunities for savings in the cost of vaccines in the Commonwealth, when viewed across all sources of funding. For example, the Division's raw claim data for calendar 2008²³ showed approximately \$18 million billed by providers (charged rates) for HPV vaccines for children, with \$15 million allowed by insurers (and less than that paid by insurers, due to cost sharing). If the state can procure HPV vaccine at a 20 percent discount from the \$15 million allowed amount, the cost of the HPV vaccine would drop to \$12 million, a savings of some \$3 million off the allowed amount. This savings is not a direct result of enacting S.B. 2195, and could be achieved without the bill's passage; therefore it is not included in the final estimate of the bill's impact. However, passage of S.B. 2195, by disengaging vaccination funding from the general fund appropriation process, may in a practical sense enable it.

3.3 Time-dependent factors

This analysis provides an estimate of the cost of this mandate for five years, 2011 to 2015. Our analysis will account for:

- Membership trends
- Cost inflation: We assume an annual per-service cost increase of three percent, measured from 2010 and raising the value for 2011 and on. ²⁴

²⁴ Roughly the 3.5 percent trend reported for HMO's in www.mass.gov/Ihqcc/.../2009_04_01_Trends_for_Fully-Insured_HMOs.doc and http://www.mass.gov/Eoca/docs/doi/Consumer/MAHMOTrendReport.pdf



We have seen documents from earlier in the decade suggesting that if the funding mechanism for DPH's vaccine purchases were to change from public revenues to a dedicated fund holding essentially private funds then DPH would lose its discount. Letter saying CDC contracts may not be used to purchase vaccines using private funds. April 26, 2004 letter from Kimberly Lane, Associate Director for Management and Operations, National Immunization Program, Centers for Disease Control and Prevention. This is not a current concern, but note that were DPH to lose its discount, providing the same number of doses to children would become much more expensive and the child immunization fee would rise substantially (potentially on the order of \$32 million, assuming a 40% discount resulting in the current \$48 million budget).

²³ These amounts are measured directly from the Division's raw claim data, without adjusting for portions of the full commercially-insured membership that might not be reflected in the raw data.

4. METHODOLOGY

4.1 Analysis steps

The analysis of S.B. 2195 is divided into two parts: estimating the impact of the mandate, and estimating the impact of the assessment. Compass estimated the impact of the mandate by taking the following steps:

- Estimate the populations covered by the mandate; i.e., identify the types of policies affected and estimate the number of covered individuals by age and insurance type
- Measure past use (per member) and insurers' expenditures for vaccines and related services and estimate dollars per member by age and insurance type
- Estimate incremental per member cost for vaccine and related services if the bill passes, using ranges of estimates for factors affecting vaccine demand and cost
- Estimate (ranges for) changes in per member cost for vaccines and related services over the next 5 years
- Estimate the impact on premiums by accounting for retention

Compass estimated the impact of the assessment with the following steps:

- Determine the approximate size of the assessment described by the bill, by referencing and adjusting the current funding the assessment would replace.
- Define and apply a sample allocation rule for the assessment to the various insurance entities described in the bill (fully-insured commercial, self-insured commercial, Medicaid).
- Estimate retention and project the impact on premiums over the next five years

4.2 Data sources

The primary data sources used in the analysis were:

- Interviews with officials in the Department of Public Health and the Division
- Government reports and data and academic literature, cited as appropriate
- Claims: The Division provided Massachusetts data from its all-payer claim database for claims containing any vaccine or administration services for most private plans

 Membership data: The Division provided membership data for the plans represented in the all-payer claim data. We also used other studies prepared for the Division, supplemented with U.S. Census data to derive trends by age group

The step-by-step description of the estimation process below addresses limitations in some of these sources.

5. Analysis

5.1 Estimating the insured population affected by the mandate

Table 1 shows the number of people potentially affected by the mandate, broken down by age and type of insurance.²⁵ As noted above, not every provision will necessarily apply to all. This analysis does not include individuals with Medicare coverage and federally-regulated "medigap" policies. We have excluded populations over age 64.

Even if the vaccination mandate of the bill does not apply to self-insured plans (other than GIC), to the extent that employers who purchase self-insured plans want to offer employees plans that meet the standards to which fully-insured plans are held, the bill may have the effect of raising the bar for vaccination coverage for self-insured plans.

The Division's membership data, representing the plans contributing to its all-payer claim database, contains 2.9 million, of which 1.7 million are fully-insured and 1.2 million self-insured. Non-residents who work in Massachusetts and are insured by policies issued in Massachusetts are not included in the Division's count and are not in the population affected by the mandate. They may, however, be present in some of the membership numbers gathered from insurance data, and so the member counts in the analysis may include insured non-residents who are not subject to the mandate. S.B. 2195 effectively applies to insurance regulated by (issued in) Massachusetts, and Massachusetts residents who commute to other states and are insured in those states are generally not included in insurance roles. As a cross-reference, according to the Kaiser Family Foundation, approximately 4.1 million Massachusetts residents are covered under non-government health plans. Kaiser Family Foundation, "Massachusetts: Health Insurance Coverage of the Total Population, states (2007-2008)", accessed 1/26/10, http://www.statehealthfacts.org/profileind.jsp?ind=125&cat=3&rgn=23>

Table 1: Membership (projected 2011)

	2011	2012	2013	2014	2015
Fully Insured					
Adult	1,725,000	1,725,000	1,725,000	1,724,000	1,723,000
Kid 0-18	631,000	629,000	628,000	627,000	627,000
Total	2,356,000	2,354,000	2,353,000	2,351,000	2,350,000
Self Insured					
Adult	1,526,000	1,526,000	1,526,000	1,526,000	1,525,000
Kid 0-18	571,000	569,000	568,000	567,000	566,000
Total	2,097,000	2,095,000	2,094,000	2,093,000	2,091,000
Commercial Total	4,453,000	4,449,000	4,447,000	4,444,000	4,441,000
Medicaid/MassHealth					
Adult	646,000	646,000	645,000	645,000	645,000
Kid 0-18	517,000	515,000	514,000	514,000	513,000
Total	1,163,000	1,161,000	1,159,000	1,159,000	1,158,000
Grand Total	5,616,000	5,610,000	5,606,000	5,603,000	5,599,000

Note we are folding into the Medicaid/MassHealth category children who are in MassHealth programs though not necessarily strictly covered by Medicaid.²⁶ GIC members are included in the fully- and self-insured categories in Table 1.

5.2 Current claim costs for vaccinations and administration

Using carrier claim data, provided by the Division, we measured the amount paid per member for 2008 claims for vaccinations and related services.²⁷ Table 2 provides a brief summary, showing the per-member-per-month dollars paid and units for 2008.²⁸ Appendix A provides more detail. Appendix B shows claim data for a different period,

June, 2010 Compass Page 17

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²⁶ MassHealth says that approximately 520,000 children are covered by MassHealth programs, compared with approximately 410,000 in Medicaid according to Census and other federal data sources. We will use MassHealth's value for children, retaining the federal values for adults. Ultimately the value for children is the only one affecting this analysis. Memo "Implications of S. 2195 on the MassHealth Program Relative to Vaccine Administration", MassHealth, January 2010.

²⁷ We excluded vaccine charges and units for vaccines not recommended for prevention of disease for the general population, such as those related to travel (e.g., for yellow fever) or for special risk situations (e.g., for rabies). The excluded charges amounted to about two percent for children, and seven percent for adults.

²⁸ Note Tables 2 and 4 express ratios between the cost of services for the age subgroup and the number of members in the age subgroup. Age breaks in Table 2 reflect categories in the Division's claim data.

Subsequent tables use age breaks defined in the statute to categorize membership data.

the year ending June 2008, superimposed over data describing vaccines and doses provided through the state's program.

Table 2: 2008 Vaccine and Administration Cost per Member per Month

		Admin Paid		Vaccine Paid	Admin Units	Vaccine Units
Fully Insured Adult (<65) Child 0-19	\$ \$	0.32 2.11	\$ \$	0.82 2.61	0.02 0.13	0.02 0.06
Self Insured Adult (<65) Child 0-19	\$ \$	0.39 2.51	\$ \$	0.98 3.22	0.02 0.13	0.02 0.06

Administration dollars and units are subject to some uncertainty, because they are based on administration procedure codes in the claims, and providers may choose to bill the service under an office visit instead, and they include administration of non-recommended vaccines. Nonetheless note that administration units are higher than vaccine units for children, suggesting that at least some of the administration of free vaccines is captured in the claim data.

5.3 Changes in vaccination costs due to S.B.2195 mandate

Table 3 summarizes our assumptions for the potential changes to the cost of vaccines due to the elimination of cost sharing and the requirement that insurers pay 100 percent of reasonable and customary fees, discussed in Section 3 above. Claim data underlying the assumptions are detailed in Appendix A. From that data, for fully-insured plans, we observed a roughly 1.6 ratio between the billed and paid amounts for vaccines. We expect reasonable and customary fees, on average, to fall between those two values, probably closer to the allowed amount, which is on average 10 percent more than the paid amount.²⁹ Note that the difference between amounts billed and paid for self-insured

²⁹ Customary and reasonable fees are a product of statistics on the prevailing costs in a geographic area. For example, the Illinois Department of Insurance defines the Usual and Customary fee as the charge "consistent with the average rate or charge for identical or similar services in a certain geographical area.

plans is less than that for fully-insured plans, most likely due to differences in benefit design.

Table 3: Estimate Ranges for Adjustments in Vaccine and Administration Costs

Due to Cost-Sharing and Reasonable and Customary Provisions

	Low	Mid	High
Fully-Insured	15%	25%	30%
Self-Insured	10%	15%	20%

Applying these assumptions to both vaccine and administration costs and combining the two yields Table 4, expressed in cost per member per month.

Table 4: Vaccine and Administration Cost per Member per Month after Change Factors

		Current		Low	Mid	High		
Fully Insured Adult (<65) Child 0-18	\$ \$		•	1.31 5.43	•	1.43 5.90	•	1.48 6.14
Self Insured		4.07		4.50		4		4.64
Adult (<65) Child 0-18	\$ \$	1.37 5.74	\$ \$	1.50 6.31	\$	1.57 6.60	\$	1.64 6.89
Cilia 0-10	ب	3.74	ب	0.51	Ų	0.00	Ų	0.05

5.4 Increase in covered costs to be paid by health insurers

Applying the estimated increase in per-member per-month costs over current levels, as shown in Table 4, to the projected annual insured membership for the next five years yields the range of estimated costs shown in Tables 5A (for fully-insured plans) and 5B (self-insured plans). The tables reflect changes in projected membership and an assumption of three percent per year for inflation in the cost of services (over the 2008).

To determine the Usual and Customary fee for a specific medical procedure or service in a given geographic area, insurers often analyze statistics from a national study of fees charged by medical providers, such as the data base profile set up by the Health Insurance Association of America (HIAA)." See http://www.insurance.illinois.gov/healthinsurance/usual_customary_fees.asp. Therefore, allowed amounts may often reflect customary and reasonable fees. However, allowed amounts may also reflect provider contracting that may constrain fees in certain situations.

base year for costs reflected in the previous tables). It should be noted that the mandate will likely not apply to self-insured plans due to federal ERISA laws.

Table 5A: Estimated Cost of Mandated Services – Fully-insured Plans

Adults (under 65) Members	1,	-2011 - 725,000	1	-2012 - ,725,000	1,	-2013 -	1,	- 2014 -	1	-2015 -	- Total -
Low estimate (\$K) Mid estimate (\$K) High estimate (\$K)	\$	3,873 6,456 7,747	\$	3,990 6,649 7,979	\$	4,109 6,849 8,219	\$	4,230 7,050 8,460	\$	4,354 7,257 8,709	\$ 20,557 34,262 41,114
Children (0-18) Members Low estimate (\$K) Mid estimate (\$K) High estimate (\$K)	\$	5,861 9,769 11,722	\$	629,000 6,018 10,030 12,036	\$	627,000 6,179 10,298 12,357	\$	627,000 6,364 10,607 12,728	\$	627,000 6,555 10,925 13,110	\$ 30,977 51,628 61,954
Total Fully-Insured Low estimate (\$K) Mid estimate (\$K) High estimate (\$K)	\$	9,735 16,224 19,469	\$	10,007 16,679 20,015	\$	10,288 17,147 20,576	\$	10,594 17,657 21,188	\$	10,909 18,182 21,819	\$ 51,534 85,889 103,067

Table 5B: Estimated Cost of Mandated Services – Self-insured Plans

Adults (under 65) Members	1,	-2011 - 526,000	1	-2012 - ,526,000	1	-2013 - ,526,000	1,	-2014 -	1,	-2015 -	- Total -
Low estimate (\$K) Mid estimate (\$K) High estimate (\$K)	\$	2,733 4,100 5,466	\$	2,815 4,223 5,630	\$	2,900 4,349 5,799	\$	2,987 4,480 5,973	\$	3,072 4,608 6,144	\$ 14,507 21,760 29,014
Children (0-18) Members		571,000		569,000		567,000		567,000		567,000	
Low estimate (\$K) Mid estimate (\$K) High estimate (\$K)	\$	4,297 6,445 8,593	\$	4,410 6,615 8,820	\$	4,526 6,790 9,053	\$	4,662 6,993 9,324	\$	4,802 7,203 9,604	\$ 22,697 34,046 45,394
Total Self-Insured Low estimate (\$K) Mid estimate (\$K) High estimate (\$K)	\$	7,030 10,545 14,060	\$	7,225 10,838 14,450	\$	7,426 11,139 14,852	\$	7,649 11,473 15,298	\$	7,874 11,811 15,748	\$ 37,204 55,806 74,408

By applying the PMPM changes to the membership of the GIC plans (and recognizing that 85 to 90 percent of GIC members are in self-insured plans) we can derive a similar

set of values for the GIC plans, shown below in Table 5C. Note that GIC membership is included in the general fully- and self-insured results.

Table 5C: Estimated Cost of Mandated Services - GIC Plans

Adults (under 65)		-2011 -	-2012 -	-2013 -	-2014 -	-2015 -	- Total -
Members	•	162,000	162,000	162,000	162,000	162,000	
Low estimate (\$K)	\$	298	\$ 307	\$ 317	\$ 326	\$ 336	\$ 1,584
Mid estimate (\$K)		454	468	482	497	512	2,413
High estimate (\$K)		597	615	633	652	672	3,169
Children (0-18)	1						
Members	ļ	61,000	61,000	60,000	60,000	60,000	
Low estimate (\$K)	\$	471	\$ 485	\$ 492	\$ 506	\$ 522	\$ 2,476
Mid estimate (\$K)		717	739	748	771	794	3,770
High estimate (\$K)		942	970	983	1,013	1,043	4,952
Total GIC							
Low estimate (\$K)	\$	770	\$ 793	\$ 808	\$ 832	\$ 857	\$ 4,060
Mid estimate (\$K)		1,172	1,207	1,231	1,268	1,306	6,182
High estimate (\$K)		1,539	1,585	1,616	1,665	1,715	8,120

5.5 Effect of the mandate on health insurance premiums

To convert medical cost estimates to premiums, we added insurer retention, i.e., the portion of premiums that represent administration costs and profit for bearing risk on covered members. Using historical retention data, we estimated a retention ratio of approximately 12 percent. Table 6A displays the resulting net effect on premiums for fully-insured plans, showing the net increase measured on a per-member per-month (PMPM) basis and an increase as a percentage of estimated premiums.

Table 6A: Estimated Incremental Impact of S.B. 2195 Mandate on Fully-Insured Plans

		-2011 -		-2012 -		-2013 -		-2014 -		-2015 -		- Mean -
Members	2	,356,000	2	2,354,000		2,352,000		2,351,000		2,350,000		
Med Exp Low (\$K) Med Exp Mid (\$K) Med Exp High (\$K)	\$	9,735 16,224 19,469	\$	10,007 16,679 20,015	\$	10,288 17,147 20,576	\$	10,594 17,657 21,188	\$	10,909 18,182 21,819	\$	10,307 17,178 20,613
Premium Low (\$K) Premium Mid (\$K) Premium High (\$K)	\$	11,062 18,437 22,124	\$	11,372 18,954 22,744	\$	11,691 19,485 23,382	\$	12,039 20,065 24,078	\$	12,397 20,662 24,794	\$	11,712 19,520 23,424
Low PMPM Mid PMPM High PMPM	\$	0.39 0.65 0.78	\$	0.40 0.67 0.81	\$	0.41 0.69 0.83	\$	0.43 0.71 0.85	\$	0.44 0.73 0.88	\$	0.41 0.69 0.83
Est Mo. Premium Premium % Rise Low Premium % Rise Mid Premium % Rise High	\$	442 0.09% 0.15% 0.18%	\$	468 0.09% 0.14% 0.17%	\$	496 0.08% 0.14% 0.17%	\$	526 0.08% 0.14% 0.16%	\$	558 0.08% 0.13% 0.16%	\$	498 0.08% 0.14% 0.17%

For fully-insured plans, the estimated mean PMPM cost of the mandate provision of S.B. 2195 over five years is \$0.41 to \$0.83.³⁰ We estimate that S.B.2195 would increase premiums by 0.08 to 0.17 percent.

Table 6B shows corresponding data for self-insured plans, without the estimated percent of premiums. For self-inured plans, we assumed a retention rate of 7.5 percent, reflecting administrative expense but no profit for bearing risk. It should be noted that the mandate will likely not apply to self-insured plans due to federal ERISA laws.

June, 2010 Compass Page 22

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³⁰ As noted in Section 3 of this report, the HPV vaccination rate for 2008 is likely to decrease in the future. While we don't have a basis for estimating the temporal pattern, the base of vaccine costs to which the percentage increases have been applied is likely to become smaller over time. If we apply the 15 percent decrease from the example in Section 3 to the mid-range mean premium value in Table 6A, we would expect the cost of the mandate to be approximately \$3 million lower. Similar percentage decreases would apply to the high and low ends of the range, and to values for self-insured plans in Table 6B.

Table 6B: Estimated Incremental Impact of S.B. 2195 Mandate on Self-Insured Plans

		-2011 -		-2012 -		-2013 -		-2014 -		-2015 -		- Mean -
Members	2	,097,000	2	2,095,000		2,094,000		2,093,000		2,091,000		
Med Exp Low (\$K)	\$	7,030	\$	7,225	\$	7,426	\$	7,649	\$	7,874	\$	7,441
Med Exp Mid (\$K)		10,545		10,838		11,139		11,473		11,811		11,161
Med Exp High (\$K)		14,060		14,450		14,852		15,298		15,748		14,882
Premium Low (\$K)	\$	7,600	\$	7,811	\$	8,028	\$	8,269	\$	8,513	\$	8,044
Premium Mid (\$K)		11,400		11,717		12,042		12,403		12,769		12,066
Premium High (\$K)		15,200		15,622		16,056		16,538		17,025		16,088
Low PMPM	\$	0.30	\$	0.31	\$	0.32	\$	0.33	\$	0.34	\$	0.32
Mid PMPM		0.45		0.47		0.48		0.49		0.51		0.48
High PMPM		0.60		0.62		0.64		0.66		0.68		0.64

5.6 Effect of the assessment on health insurance premiums

S.B. 2195 provides that money collected from insurers in the form of the childhood immunization fee will support the Child Vaccine Trust Fund. The budget for FY 2010 is approximately \$47 million. To that we add another \$1 million for the estimated annual cost of operating the Immunization Registry. It has been asserted that the Registry might offer some benefits of its own, including reducing vaccine waste and duplication, which might offset, or more than offset, the cost of the Registry to those paying the assessment. In addition the Registry might reduce administrative costs within provider offices; that benefit, however, would not pass directly to assessment payers, though it might help to reduce overall health care costs over time through changes in administration reimbursement rates. We are not aware of empirical evidence documenting cost savings related to vaccine registries and have not included an explicit impact in our estimates.

Table 7 reflects a five year projection of one possible approach to allocating the assessment to support the Fund. The table assumes Medicaid contributes to the assessment, assumes a three percent annual growth in expenditures, and apportions the

³¹ Estimate from Department of Public Health white paper: "Immunization Financing Crisis in Massachusetts -- The Need for Secure Funding, Reimbursement and Tracking", February 4, 2009.

assessment by child membership. This analysis assumes no other vaccines are added to the program.

Table 7: Allocation across Payors of Projected Child Vaccine Trust Fund Assessment (\$000's)

	-2011 -	-2012 -	-2013 -	-2014 -	-2015 -	- Total -
Fully Insured	18,100	18,700	19,300	19,800	20,400	96,300
Self Insured	16,400	16,900	17,400	17,900	18,400	87,000
Commercial Total	34,500	35,600	36,700	37,700	38,800	183,300
Medicaid/MassHealth	14,900	15,300	15,800	16,300	16,700	79,000
Total	49,400	50,900	52,500	54,000	55,600	262,400

To convert the impact of the assessment to premiums, we added insurer retention, i.e., the portion of premiums that represent administrative expense and profit for bearing risk on covered members. Using historical retention data, we estimated a retention ratio of approximately 12 percent. Table 8A displays the resulting net effect on premiums for fully-insured plans, showing the net increase measured on a per-member per-month (PMPM) basis and an increase as a percentage of estimated premiums.

Table 8A: Estimated Incremental Impact of Assessment on Fully-Insured Plans

		-2011 -		-2012 -		-2013 -		-2014 -		-2015 -	-Mean -
Members	2,356,000		2,354,000		2,352,000		2,351,000		2,350,000		
Assessment (\$K)	\$	18,100	\$	18,700	\$	19,300	\$	19,800	\$	20,400	\$ 19,260
Premium Impact (\$K)	\$	20,568	\$	21,250	\$	21,932	\$	22,500	\$	23,182	\$ 21,886
РМРМ	\$	0.73	\$	0.75	\$	0.78	\$	0.80	\$	0.82	\$ 0.78
Est Mo. Premium Premium % Rise	\$	442 0.16%	\$	468 0.16%	\$	496 0.16%	\$	526 0.15%	\$	558 0.15%	\$ 498 0.16%

For fully-insured plans, the estimated average PMPM cost of the assessment provision of S.B. 2195 over five years is about \$0.78. We estimate that the assessment provision of S.B.2195 would increase premiums by about 0.16 percent.

Table 8B shows corresponding data for self-insured plans, without the estimated percent of premiums. For self-inured plans, we assumed a retention rate of 7.5 percent, reflecting administrative expense but no profit for bearing risk.

Table 8B: Estimated Incremental Impact of Assessment on Self-Insured Plans

		-2011 -		-2012 -		-2013 -		-2014 -		-2015 -	- Mean -
Members	2,097,000		2,095,000		2,094,000		2	2,093,000	2	2,091,000	
Assessment (\$K)	\$	16,400	\$	16,900	\$	17,400	\$	17,900	\$	18,400	\$ 17,400
Premium Impact (\$K)	\$	17,730	\$	18,270	\$	18,811	\$	19,351	\$	19,892	\$ 18,811
РМРМ	\$	0.70	\$	0.73	\$	0.75	\$	0.77	\$	0.79	\$ 0.75

CONCLUSION

Table 9 summarizes the impacts of the mandate and assessment provisions of S.B. 2195.

- All values are projected averages over 5 years.
- Mandate values reflect the midpoint of the estimate and could be lower or higher.
- Premium impact reflects retention (which is not relevant to MassHealth)
- Note the sum of the assessment column reflects the average of the assessment budget projected over five years.

Table 9: Estimated Incremental Impact of Mandate and Assessment (5 year average) (\$000's, except PMPM)

Plan Category	Mandate	Ass	sessment	Total	Premium Impact	PMPM Impact
Fully-Insured	\$ 17,178	\$	19,260	\$ 36,438	\$ 41,407	\$ 1.47
Self-Insured	\$ 11,161	\$	17,400	\$ 28,561	\$ 30,877	\$ 1.23
Total Commercial	\$ 28,339	\$	36,660	\$ 64,999	\$ 72,284	
Medicaid/MassHealth	-	\$	15,800			

The PMPM impact for fully-insured plans translates to 0.30 percent of premiums.

Because S.B. 2195 leaves the apportionment of the assessment to the Division, these numbers are only one of several possible scenarios, but the order of magnitude of the impact on fully-insured plans is probably reliable. Should changes in the bill, or subsequent rule-making, modify the set of plans subject to the assessment, or specify an allocation method different than the sample method used here, the assessed amounts will change. For example, should it be determined that Medicaid/MassHealth is not subject to the assessment, its share would be reallocated among the other assessment payers. If regulators interpret S.B. 2195 to change significantly billing practices for vaccine administration the impact of the mandate portion of the bill could be higher by a substantial margin.

APPENDICES

Appendix A: Detail of Claim Data

Appendix B: Vaccine Cost and Units by Type and Funding Source

Appendix A: Detail of Claim Data

Appendix Table A-1: PMPM Values for Paid, Allowed, and Billed Vaccine and Administration Dollars and Units, for Recommended Vaccines and HPV Vaccines, Based on the Division's 2008 All-Payer Data

	All Vaccines												HPV Vaccines								
		Admin		Vaccine		Admin		Vaccine		Admin		Vaccine	Admin	Vaccine	,	/accine	,	Vaccine		Vaccine	Vaccine
Segment		Paid		Paid		Allowed		Allowed		Billed		Billed	Units	Units		Paid	ı	Allowed		Billed	Units
Fully-Insured																					
Adult (<65)	\$	0.32	\$	0.82	\$	0.37	\$	0.93	\$	0.59	\$	1.43	0.02	0.02	\$	0.33	\$	0.37	\$	0.53	0.00
Child 0-19	\$	2.11	\$	2.61	\$	2.33	\$	2.86	\$	3.76	\$	3.87	0.13	0.06	\$	1.25	\$	1.37	\$	1.78	0.01
Self-Insured																					
Adult (<65)	\$	0.39	\$	0.98	\$	0.40	\$	1.02	\$	0.57	\$	1.42	0.02	0.02	\$	0.38	\$	0.39	\$	0.51	0.00
Child 0-19	\$	2.51	\$	3.22	\$	2.58	\$	3.33	\$	3.90	\$	4.14	0.13	0.06	\$	1.57	\$	1.62	\$	1.92	0.01

Appendix Table A-2: Values for Paid, Allowed, and Billed Vaccine and Administration Dollars and Units, for Recommended Vaccines, Based on 2008 All-Payer PMPM Data and Projected 2011 Membership

Segment	Members	Admin Paid	Vaccine Paid	Admin Allowed	Vaccine Allowed	Admin Billed	Vaccine Billed	Admin Units	Vaccine Units
Fully-Insured									
Adult (<65)	1,706,656 \$	6,507,628 \$	16,872,480 \$	7,670,628 \$	19,119,814 \$	11,998,409 \$	29,195,129	353,779	421,363
Child 0-18	624,498	15,849,703	19,540,456	17,482,426	21,432,829	28,193,414	28,974,913	956,841	486,486
GIC (FI)									
Adult (<65)	18,245	69,569	180,373	82,002	204,398	128,267	312,106	3,782	4,505
Child 0-18	6,826	173,250	213,592	191,097	234,278	308,176	316,718	10,459	5,318
GIC (SI)									
Adult (<65)	144,045	668,321	1,692,714	689,233	1,757,277	981,865	2,458,613	29,013	35,119
Child 0-18	53,894	1,625,683	2,085,548	1,671,091	2,153,579	2,521,132	2,677,739	85,603	41,766
Self-Insured									
Adult (<65)	1,382,153	6,412,753	16,242,127	6,613,405	16,861,632	9,421,306	23,591,165	278,388	336,975
Child 0-18	517,130	15,598,943	20,011,490	16,034,646	20,664,273	24,191,060	25,693,749	821,389	400,757
Commercial Total	4,453,446 \$	46,905,850 \$	76,838,781 \$	50,434,526 \$	82,428,080 \$	77,743,630 \$	113,220,133	2,539,253	1,732,288

June, 2010 Page 28

Appendix B: Estimated Vaccine Cost and Units by Type and Funding Source

Appendix Table B: Vaccines Provided by DPH and Paid for by Carriers: Year Ending June 2008¹

	 Vaccin	e C	ost	 	Vaccine Units								
Vaccine Type	State		Carriers	Total	Vaccine Type	State	Carriers	Total					
DT	\$ 68,300	\$	4,800	\$ 73,100	DT	3,000	500	3,500					
DTaP	1,037,300		250,300	1,287,600	DTaP	82,000	43,700	125,700					
Flu	5,555,600		7,745,700	13,301,300	Flu	497,000	652,500	1,149,500					
Gammastan	11,300		-	11,300	Gammastan	400	-	400					
HEP A	1,438,200		2,681,000	4,119,200	HEP A	106,400	79,000	185,400					
HEP B	1,989,800		2,240,200	4,230,000	HEP B	106,100	38,400	144,500					
Hib	790,100		45,900	836,000	Hib	95,000	25,700	120,700					
HPV	-		45,122,600	45,122,600	HPV	-	323,700	323,700					
IPV	677,500		213,600	891,100	IPV	60,200	19,800	80,000					
MCV4	7,260,400		10,368,900	17,629,300	MCV4	97,600	132,100	229,700					
MMR	1,585,100		269,200	1,854,300	MMR	88,200	25,100	113,300					
PCV7	10,126,400		893,300	11,019,700	PCV7	156,900	59,800	216,700					
Pediarix	5,127,300		-	5,127,300	Pediarix	106,800	-	106,800					
PPV23	1,476,800		-	1,476,800	PPV23	99,400	-	99,400					
Rotavirus	5,212,600		1,976,700	7,189,300	Rotavirus	92,400	45,300	137,700					
Tdap	1,970,000		6,697,300	8,667,300	Tdap	63,100	211,900	275,000					
Varicella	3,192,000		2,829,400	6,021,400	Varicella	53,700	82,900	136,600					
Other	-		7,497,800	7,497,800	Other	-	69,700	69,700					
Total	\$ 47,518,700	\$	88,836,700	\$ 136,355,400	Total	1,708,200	1,810,100	3,518,300					
Admin		\$	42,209,300		Admin Units		2,546,200						

June, 2010 Page 29

¹ All values are approximate. All data are for year ending June 2008 (not the year that is the basis for the other estimates in the report). State values come from data from the Department of Public Health. Carrier dollar and unit value come from the Division's claim data but have been increased proportionately to reflect the estimate of the full commercial membership. Carrier data includes vaccines that may not be recommended and may not be affected by S.B. 2195 (e.g., for rabies). The units table assumes a rough approximation of units and doses. In some cases, vaccines have been grouped together for convenience. Federal vaccine funds are not shown; generally, they fund vaccines for income-eligible people not covered by the commercial plans that are the focus of this analysis. See the body of the analysis for a discussion of the relative size of the costs of HPV vaccine and how they may change over time.

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